Post Coverage Analysis of Transmyocardial Revascularization among Medicare Beneficiaries (TMR)
Final Report

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Contract # 500-01-0043
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TMR Executive Summary

Transmyocardial revascularization (TMR) is a treatment for ischemic heart disease in which a laser is used to make a hole through the myocardium into the ventricle. The treatment is directed to areas of myocardium in which the blood supply from the coronary arteries is inadequate. TMR can either be done as a sole procedure or it can be done in addition to coronary artery bypass grafting (CABG) in an individual who has some areas of myocardium amenable to bypass and others that are not; in either case it requires opening the chest and exposing the heart.

Clinical trials have demonstrated a benefit from TMR compared to no treatment for patients who could not have perfusion restored through more traditional means such as angioplasty or CABG.[1, 2] There is not good clinical evidence that anginal symptoms are reduced when TMR is done in conjunction with a CABG.[3]

Medicare coverage started in July 1999 for TMR alone and for TMR in conjunction with CABG (TMR+CABG) in October 1999. This report examines the use of TMR and TMR+CABG within Medicare in the two calendar years following the CMS coverage approval. Further, we describe the one-year post-procedure outcomes and utilization for the Medicare TMR and TMR+CABG populations. To provide context and reference, we examine the outcomes and utilization for individuals undergoing CABG in Medicare.

Methods

The first step in the analysis was to create the analytic files for the TMR and CABG populations. This entailed: 1) identifying the population in the Medicare claims and obtaining their claims, 2) cleaning the claims files, 3) creating analytic cohorts from the claims and enrollment files.

Four steps were undertaken to identify and obtain the claims. First, the HICs were extracted from 100% NCH Carrier, Inpatient and Outpatient files for 2000 and 2001 for all individuals with a HCPCS or ICD-9 code for TMR. This was repeated for CABG. Next, finder files were created from the HICS identified. These finder files had duplicates removed and were cross-referenced. Finally, this cross-referenced file was used to extract all claims for the individuals from the Carrier, Inpatient, Outpatient, Skilled Nursing Facility, Home Health Agency, Hospice, and Durable Medical Equipment, and Denominator files for the years 1998-2002. These files were cleaned by excluding denied and duplicate claims and fields irrelevant to the analysis were deleted. Multiple claims relating to the same hospital stay were pooled.

Creating the analytic cohorts

There is the possibility, particularly with newly introduced procedures, of miscoding within claims data. There is more certainty that claims represent actual care delivered when there is consistency within claims. For TMR and CABG we would expect, since they are performed in the hospital, that there would be both a physician (i.e., Carrier) claim and a hospital (i.e., Inpatient) claim for the procedure(s). One may conclude that individuals with both a physician and hospital claim for TMR or TMR+CAGB are more likely to have actually undergone the procedures than individuals who have only one type of claim or the other. On the other hand, use of such a strict criterion to identify subjects will miss individuals who actually underwent a TMR or TMR+CABG procedure but were miscoded in one of the claims files.

Because there are analytic strengths and weaknesses to both the strict and relaxed criterion for patient identification, we examined two cohorts, those with two consistent claims for TMR or TMR+CABG (Exact Match) and those individuals with any claims for TMR or TMR+CABG (All Possible) Using the stricter identification criterion, we identified 636 individuals who underwent TMR alone in 2000 and 2001 and 2038 who underwent TMR+CABG. Using the less restrictive criterion 845 TMR alone and 3063 TMR+CABG individuals were identified.

Establishing coverage

If an individual does not have Medicare fee for service (FFS) coverage for a portion of the study interval, no information about the individual is available for that period of time. For example, if an individual does not have coverage in the months before TMR, any hospitalizations before the TMR will not be observed. This can have a number of repercussions in the analysis and so coverage needs to be assessed and where applicable, adjusted for. We examined the monthly Part A and Part B coverage, and monthly HMO indicators in the Denominator files and assessed contiguous coverage before and after the procedure for each individual. The rate of coverage for the full two years before surgery for Part A and Part B for the TMR, TMR+CABG and CABG groups ranged from 80% to 85% but there were no statistically significant differences between the groups. The rates of coverage for the year after the surgery was similar but was statistically significantly lower for the TMR alone group compared to the CABG group (79.3% vs 88.0%; p<.01). This difference was primarily due to greater mortality within the TMR alone group.

Analytic variables

Age was calculated as time from birth date (from Denominator file) to the date of surgery. Race and gender were extracted from Denominator files.

We assessed comorbidities using the Charlson comorbidity index.[4] It also partially assesses severity of coronary vascular disease in that it includes measures of the presence of a claim for a myocardial infarction. We examined all of the Inpatient and Carrier claims for the two years prior to the TMR and/or CABG procedure to identify comorbid conditions, including claims at the time of surgeries.

Two variables were created for all hospitalization before the procedure: 1) presence of any hospitalization and 2) number of hospitalizations per person year. Two variables were created for CHD hospitalization before the procedure: 1) presence of any CHD hospitalization and 2) number of CHD hospitalizations per person year. A CHD hospitalization was defined as one with a claim which contained an ICD9 diagnosis code beginning with '410', '411', '412', '413', and '414' as primary diagnosis.

Because essentially all subjects had Carrier claims, only the number of claims per person-year was calculated rather than whether claims were present or not. The number of physicians' services per person-year in Carrier claims was calculated by examining the Carrier claims for each individual for the year before the procedure that contained a BETOS code for "evaluation and management" in their line trailer.

Similar variables were created for utilization for the year after the procedure. These included: 1) presence of any hospitalization, 2) number of hospitalizations per person year, 3) presence of any CHD hospitalization, 4) number of CHD hospitalizations per person year, and 5) number of physicians services per person year in Carrier claims. We also assessed the time to rehospitalization and time to CHD rehospitalization.

Mortality information was obtained from the Denominator file. Data through March 31, 2003 was used for the mortality analysis as the files were updated to that date.

Findings

We found that the number of TMR procedures done was relatively stable between the years 2000 and 2001 although there was a decrease in the number of procedures done that did not accompany a CABG. These procedures were done in a large number of institutions across the country rather than being concentrated in only a few.

Compared to the Medicare population as a whole, both the population of patients getting TMR and TMR+ CABG was on average younger and more likely to be: male, white, disabled. They were similar in gender and race to the Medicare population undergoing CABG. Both populations also had a higher level of comorbidity than did the population undergoing CABG alone.

The mortality rate in the year following the procedure was greatest for the patients who underwent TMR alone, followed by those who underwent TMR+CABG, and finally CABG alone. The difference between the TMR+CABG and CABG groups disappeared after controlling for comorbidities, suggesting that the comorbidities were driving the higher mortality rate in the TMR+CABG group.

Prior to the procedure, the TMR alone group had the highest overall hospital utilization, followed by the TMR+CABG group. This higher utilization persisted in the year after the procedure. Unlike the findings for the TMR alone group, the overall hospitalization rates of the TMR+CABG and CABG alone groups were similar. The best outcome for a change in hospital utilization would be a decrease in hospitalizations after the procedure, or the smallest increase in hospitalizations. The TMR alone group did best in this regard, having a smaller increase in hospitalizations than either the TMR+CABG or CABG groups.

As was the case with overall hospitalizations, prior to the procedure, the TMR alone group had the highest CHD hospital utilization, followed by the TMR+CABG group. This difference persisted after the procedure as well. Yet, the TMR alone group had the most favorable change in CHD hospital utilization; CHD hospitalizations decreased in all three groups but was greatest in the TMR alone group.

As was the case for hospital utilization, prior to the procedure the TMR alone group had the highest level of utilization of physician services and this persisted after the TMR procedure. All three groups had an increase in their use of physician services after the TMR or CABG procedure. The TMR+CABG group had the greatest increase.

Discussion

In the two years following the approval of coverage for TMR, it remained a rather infrequent procedure within the Medicare population and there was no evidence that its use was increasing. Our findings suggest that this is not due to TMR being limited to a few centers and has simply not yet diffused geographically. Rather, there is a fairly wide geographic distribution and nowhere is it being done at a great rate.

Although there is greater support from clinical trials for the effectiveness of TMR alone than TMR+CABG, TMR+CABG is still the more common procedure within the Medicare population. This may result from the fact that the clinical threshold for performing a TMR in the setting of CABG is lower for TMR alone as the patient has is already undergoing a throracotomy.

The conclusions regarding the higher mortality in the TMR group are clearly limited by the lack of good comparisons. CABG itself has a fairly modest effect on mortality; hence the greater mortality rate seen in the TMR alone group must arise either because the patients are sicker overall or because the TMR procedure is contributing to their mortality. Although we are not able to assess it directly in this study, we do know that they had more severe coronary artery disease on average as they had lesions that were not amenable to bypass. Clinical trials of TMR have not shown either survival benefit or harm from TMR alone compared to those treated medically. Frazier et. al.[1]found an 85% one year survival rate in the TMR patients and 79% in the medically treated patients (a non-significant difference). Further, Allen et. al.[2] found a 89% one year survival for those randomized to TMR and 84% for those randomized to medical therapy (a non-significant difference). These rates are similar to the 80.8% one year survival we found in the Medicare population in general undergoing TMR alone. These numbers suggest that when TMR is used in a general population, the mortality outcomes are similar to that seen in the clinical trials of TMR and the greater mortality seen in this population compared to those undergoing CABG relates to the worse medical status of this group.

We are able to draw more conclusions about mortality for the TMR+CABG population. Again, it is expected that they likely have more severe coronary artery disease on average as they too have regions of myocardium that are not amenable to bypass. Yet their overall mortality rate is, after accounting for their higher comorbidity, no worse than the group getting bypass alone suggesting that the TMR procedure did not contribute to mortality in this population.

The results from the utilization analysis may suggest that the TMR alone procedure may have beneficial results. Assuming that patients who are doing better clinically utilize fewer services, the smaller changes in utilization for the TMR alone group compared to the other groups for hospitalizations and physicians services suggests that these patients may be receiving benefit from the procedure. Yet it is not possible to exclude the possibility that this instead represents decisions to limit treatment for these individuals because of their severe disease or other analytic factors.

The findings from the TMR+CABG group overall seem reassuring. The with the exception of the changes in the use of physicians services, the changes in utilization for the TMR+CABG group are no worse than the CABG alone group suggesting that the TMR did not do harm; whether it provided benefit cannot be ascertained.

Analysis of claims data is at a disadvantage compared to clinical trials when examining TMR outcomes such as symptoms and functional status. Yet unlike clinical trials, analysis of claims data is able to give us a broad picture of the use of TMR and its effect on mortality and utilization. Although this broad but limited examination may not allow firm conclusions, it can raise flags where outcomes are not what would be expected from the clinical trials. We identified no such flags. Within the limits of these analyses, we found nothing that suggests that TMR and TMR with CABG when applied to the general Medicare population results in outcomes different than those seen in the clinical trials of the procedures.

Transmyocardial Revascularization Final Report:

Introduction:

Transmyocardial revascularization (TMR) is a treatment for ischemic heart disease in which a laser is used to make a hole through the myocardium into the ventricle. The treatment is directed to areas of myocardium in which the blood supply from the coronary arteries is inadequate. The original theory, which was based upon observations of the anatomy of other species, was that this would allow blood to perfuse the myocardium directly from the ventricle. Although anatomic studies have not demonstrated that the holes created remain patent and that the treated myocardium receives perfusion from the ventricles, clinical trials have demonstrated a benefit from TMR compared to no treatment for patients who could not have perfusion restored through more traditional means such as angioplasty or coronary artery bypass grafting (CABG).[1, 2]

TMR can either be done as a sole procedure or it can be done in addition to a CABG in an individual who has some areas of myocardium amenable to bypass and others that are not. In this case the patient undergoes a routine CABG with a TMR performed on the areas of myocardium that could not be helped by bypass. Whether performed as a stand alone procedure or as an additional treatment in the course of a CABG, the TMR requires the placement of the laser on the outside of the heart and therefore is done in the course of a thoracotomy. Unlike the case for TMR done as a stand alone procedure, there is not good clinical evidence that anginal symptoms are reduced when TMR is done in conjunction with a CABG.[3]

In April 1999 CMS approved the coverage of TMR as a stand-alone procedure with coverage starting July 1999. This was amended in October 1999 to include TMR done in conjunction with a CABG. This report examines the population of TMR and TMR with CABG (TMR+CABG) patients in the two calendar years following the CMS coverage approval. We examine the use of the procedures and the characteristics of the individuals who underwent the procedures. Further, we describe outcomes and utilization in the year following the procedure. We also examine a Medicare cohort who underwent CABG in those years. Given that there are differences between the TMR and CABG populations that cannot be completely controlled for, this comparison is provided to give context to the results of the TMR analysis rather than serve as an actual control group. That is, it allows one to judge whether individual findings such as mortality rates are large or small by providing a similar although not identical group of patients.

Methods:

The first step in the analysis was to create the analytic files for the TMR and CABG populations. This entailed:

- 1. Identifying the population in the Medicare claims and obtaining their claims
- 2. Cleaning the claims files
- 3. Creating analytic cohorts from the claims and enrollment files.

Identifying the population and obtaining claims:

TMR
In order to identify the TMR cohort and obtain their claims we undertook the following procedures:

Step 1: Extract all HICs with either an ICD-9 Procedure code or HCPCS of TMR

Using DESY, we requested all HICs with:

> HCPCS = 33140 (TMR, separate procedure) or 33141 (TMR with other open cardiac procedure
> *OR*
> ICD-9 Procedure code = 36.31 (open chest TMR) or 36.32 (Other TMR)

Occurring in the:
2000 100% NCH Carrier file (HCPCS Only)
2001 100% NCH Carrier file (HCPCS Only)
2000 100% NCH Inpatient file
2001 100% NCH Inpatient file
2000 100% NCH Outpatient file
2001 100% NCH Outpatient file

Step 2: Create Finder files

a) We merged all HICs from the 2000 Carrier, Inpatient and Outpatient files created in Step 1 to create a finder file of all HICs having a code for TMR for Year 2000.
b) We merged all HICs from the 2001 Carrier, Inpatient and Outpatient files created in Step 1 to create a finder file of all HICs having a code for TMR for Year 2001.

Step 3: Eliminate Duplicates and Cross Reference
a) Using the Year 2000 Finder file created in Step 2a, we eliminated duplicate HICs and cross referenced (DSAF Leg 1)
b) Using the Year 2001 Finder file created in Step 2b, we eliminated duplicate HICs and cross referenced (DSAF Leg 1)
c) We merged the Year 2000 and 2001 Cross-reference Finder Files and eliminated duplicates

Step 4: Extract all claims of the identified TMR cohort
a) Using the merged year 2000 and 2001 Cross-reference Finder File created in Step 3c as an input to DESY, we extracted all claims for these beneficiaries from the following files for the years 1998 - 2002:
100% NCH Carrier file
100% NCH Inpatient file
100% NCH Outpatient file
100% NCH Skilled Nursing Facility (SNF) file
100% NCH Home Health Agency (HHA) file
100% NCH Hospice file
100% NCH Durable Medical Equipment (DME) file
b) Using the merged year 2000 and 2001 Cross-reference Finder File created in Step 3c as an input to DSAF (Leg 1), we extracted all records for these beneficiaries from the following file for the years 1998 - 2002:
100% Denominator file

CABG
The claims for the CABG cohort were identified in a similar way. The only difference was in the creation of the finder file, which required different HCPCS and ICD9 procedure codes. Specifically we:
Step 1: Extract all HICs with either an ICD-9 Procedure code or HCPCS code of CABG
Using DESY, we requested all the following HICs:
Venous
- 33510 single venous graft
- 33511 two grafts
- 33512 three
- 33513 four
- 33514 five
- 33516 six or more grafts

Arterial-venous (must report arterial and arterial-venous)
- 33517 arterial graft(s), single vein graft
- 33518 two venous
- 33519 three
- 33521 four
- 33522 five
- 33523 six or more

Re-operation
- 33530 CABG more than one month after original operation

Arterial
- 33533 using one arterial graft
- 33534 using two
- 33535 using three
- 33536 using four or more
- Coronary Endarterectomy
- 33572 in addition to CABG

OR

ICD-9 Procedure codes:

- 36.1 Bypass anastomosis for heart revascularization
- 36.10 Aortocoronary bypass for heart revascularization, NOS
- 36.11 Aortocoronary bypass of one coronary artery
- 36.12 Aortocoronary bypass of two coronary arteries
- 36.13 Aortocoronary bypass of three coronary arteries
- 36.14 Aortocoronary bypass of four or more coronary arteries
- 36.15 Single internal mammary-coronary artery bypass
- 36.16 Double internal mammary-coronary artery bypass
- 36.17 ABD-Coronary Artery Bypass
- 36.19 Other bypass anastomosis for heart revascularization

Occurring in the:

- 2000 100% NCH Carrier file (HCPCS Only)
- 2001 100% NCH Carrier file (HCPCS Only)
- 2000 100% NCH Inpatient file
- 2001 100% NCH Inpatient file
- 2000 100% NCH Outpatient file
- 2001 100% NCH Outpatient file

Step 2 through 4

The subsequent steps for identifying the claims for the cohort of patients who underwent CABG are the same as those outlined above for the TMR population.

Cleaning the claims files:

Relevant variables were selected for Inpatient and Carrier claims and Denominator records. These variables included beneficiary information (HIC, state and zip residence, birth date, and death status and date), demographic information (race and sex), Medicare information (Medicare eligibility status, monthly coverage status and HMO status), clinical information (diagnosis and procedure and associated dates), and payment information.

Denied Carrier claims were excluded. Duplicate claims, based on HIC, procedure type and date, were also excluded from the cohort dataset. Non-excluded claims were used to form study cohorts, and perform comorbidity assessment and outcome analysis.

Procedure claims in the Carrier file were identified as those having a TMR and/or CABG HCPCS procedure code in the line item trailer. Similarly, procedure claims were identified in the Inpatient file as those having TMR and/or CABG ICD9 procedure codes in the procedure trailer. The specific codes used were the same as those used for creating the finder files as discussed above. These claims were then sorted by HIC, procedure type and date.

To account for multiple Carrier claims for one hospital stay, we pooled Carrier claims into one summary record if the reported procedure dates occurred within 7 days. The expense date reported in the line item was used as the procedure date. Claims were sorted by HIC, procedure date, and procedure type. Within individuals (those with identical HICs) those claims that had procedure dates within seven days were then pooled together. The pooled claim was classified as "TMR alone" if all related Carrier claims showed TMR procedures only, as "TMR+CABG" if the pooled claims included both TMR and CABG claims. The earliest date of these related claims was recorded as the procedure date for subsequent analysis. Similar steps were conducted in Inpatient claims to classify the procedures done.

Six individuals were found to have more than one TMR procedure in 2000 and 2001. For these individuals, the latest TMR procedure was used as the index procedure in the creation of the analytic cohorts.

The identification of the CABG procedure claims was done in the same way as the TMR claims except that only the Inpatient claims were used for identifying the CABG procedures.

Creating the analytic cohorts:

There is the possibility of miscoding within claims data. This may be even more of an issue when a procedure is newly introduced. There is more certainty that claims represent actual care delivered when there is consistency within claims. For TMR and CABG we would expect, since they are performed in the hospital, that there would be both a physician (i.e., Carrier) claim and a hospital (i.e., Inpatient) claim for the procedure(s). One may conclude that individuals with both a physician and hospital claim for TMR or TMR+CAGB are more likely to have actually undergone the procedures than individuals who have only one type of claim or the other. Therefore, to establish a cohort that we were confident underwent TMR or TMR+ CABG, we identified individuals who had a concurrent (i.e., within seven days) hospital and physician claim for TMR or TMR+CABG.

The procedure claims described above were used for matching. For each patient (identified by HIC), the procedure dates were compared for the Carrier and Inpatient procedure claims. A date difference within 7 days was considered a matched. Because an individual could have had a TMR, CABG or both identified in each file, it was possible that the procedure date could match in the files but that the procedure(s) could be different. We subsequently examined how the types of procedures matched between the two files.

The results of the matching, between the Inpatient and Carrier claims for the population of patients with a TMR claim, is shown in Table 1. 3924 individuals were identified with a TMR claim and their records were obtained. Of these individuals 628 had a TMR claim (and no CABG claim) in both the Carrier and Inpatient files. An additional 1633 individuals had both a TMR and a CABG claim identified in both the Carrier and Inpatient files. This latter group is presumed to have undergone a TMR procedure during the CABG procedure. There were an additional 8 individuals who had a Carrier claim with HCPCS of 33999 which matched to a TMR claim in the Inpatient file and 405 who had a Carrier claim with HCPCS of 33999 and a CABG claim which matched to a TMR and CABG claim in the Inpatient file. The 33999 code, although not specific to TMR, was used for TMR prior to the time when the official HCPCS code was established, and therefore, in this context is assumed to represent claims for TMR. There were 1250 individuals representing 32% of the population who did not have claims that matched for both time and type of procedure in the Inpatient and Carrier files.

We hypothesized that the high percentage of unmatched claims between the Inpatient and Carrier files could be due to a too restrictive time criteria. We found that if we dropped the time criteria completely and accepted any claims for TMR and CABG within the two years of claims obtained, an additional 43 individuals would match. Yet many of these are likely not true matches as they may have been either prior or subsequent procedures rather than concurrent procedures. Given that the number of additional matches identified is so small relative to the number that did not match and that one cannot be confident that the additional matched claims represented the same procedure, we elected to use the time criteria (claims within a week) in creating the analytic cohort.

In the restrictive approach to defining a cohort, one includes only those subjects with a claim in both the Inpatient and Carrier files. In this case this approach has the advantage that one can be reasonably certain that effects seen are in a population that truly underwent TMR or TMR+CABG. Such a restrictive approach is frequently taken in the analysis of Medicare claims—individuals with unmatched claims are simply excluded from the analysis. When it is a small percentage of the total population, excluding them is unlikely to significantly affect the results. However, in this case, where a third of the population had unmatched claims, there is a greater possibility that dropping the unmatched claims would give biased results.

An alternative to the restrictive cohort would include any patient with a TMR procedure, regardless of whether a claim appeared in both the Inpatient and Carrier files. The advantage of this cohort is that it is less likely that patients who actually underwent TMR will be excluded. The disadvantage is that the cohort is likely to contain individuals who did not undergo the TMR procedure. Therefore, the results may be biased.

As there are advantages and disadvantages to both the restrictive and non-restrictive cohorts, we elected to examine two cohorts, one restrictive and one liberal in the definition of an individual undergoing a TMR procedure. How the cohorts were defined from the matching of the Carrier and Inpatient files is illustrated in Figure 1. The first cohort, called the “Exact match”, includes only those individuals who met the restrictive definition discussed above in which the same procedures are found in the Carrier and Inpatient files. The second cohort called “All Possible” defines a subject by the sum total of claims in the Carrier and Inpatient files within the seven-day time window surrounding the TMR procedure. For example, an individual who had a Carrier claim for a TMR alone and an Inpatient claim for a CABG alone within seven days was classified in this cohort as having undergone a TMR+CABG; an individual with a physician claim for TMR but no hospital claim was classified as TMR. In this way all of the subjects who were identified as having a TMR in either the Carrier or Inpatient file were included in the analysis. Within the records obtained, 16 subjects did not have a TMR in either the Inpatient or Carrier file and were excluded from this analysis. This group would have had a claim indicating TMR procedure somewhere (e.g., Outpatient file) but probably didn’t go through the TMR procedure. The numbers of patients in each category of mismatch (e.g., Carrier claim for TMR but no Inpatient claim) is shown in Table 1.

The number of individuals within the TMR and TMR+CABG cohorts using the more restrictive “Exact match” criterion and the more liberal “All Possible” criterion is shown in Table 2.

The CABG cohort was not subjected to the matching process described above because it was felt less likely that there would be a significant number of mismatches in the CABG population and because as a comparison group the element of bias was felt to be of less importance. Cases identified through the Inpatient claims were sufficient to represent the whole CABG population. The CABG cohort was identified by selecting 20% of the total population of patients, i.e. those with the ninth HIC number as a “5” or “9”.

Establishing Coverage:

If an individual does not have Medicare fee for service (FFS) coverage for a portion of the study interval, no information about the individual is available for that period of time. For example, if an individual does not have coverage in the months before TMR, any hospitalizations before the TMR will not be observed. This can have a number of repercussions in the analysis. First, coverage needs to be taken into account when analyses of rates over time are undertaken because rates will be biased downward when subjects have incomplete coverage. For example, if an individual has only six months of coverage following the TMR and one assesses the number of hospitalizations in the year after the TMR, the months of coverage needs to be accounted for, as the observation period is in reality only six months.

It is also important to examine coverage because it can cause bias in comparing groups. Because there may be a correlation between lack of coverage and other characteristics of the subjects that may affect the outcomes of interest, it is important to examine coverage both within a cohort and between cohorts. One may have more confidence in the results from individual groups and in comparisons between groups if the rates of non-coverage are low and comparable between groups.

We examined the monthly Part A and Part B coverage, and monthly HMO indicators in the Denominator files. We considered only contiguous coverage before and after the procedure. To determine coverage before the procedure, we started at the time of the index procedure for each individual and examined each month going back in time until a month without Part A or Part B coverage (as appropriate) or HMO coverage was encountered. To determine coverage after the index procedure, the process was repeated going forward in time. In this way, we determined the number of months of contiguous Part A and Part B FFS coverage before and after the index procedure for each subject.

As Table 3 shows, approximately 84% of each of the cohort groups had Part A FFS for the two years prior to the TMR or CABG and there was little difference between the groups. Further, as Figure 2 shows, the pattern of obtaining coverage prior to the procedure is similar between the cohorts; no cohort has a spike of individuals gaining coverage proximal in time to the procedure. The patterns for Part B FFS and the “All Possible” cohort were similar (not shown). There was some difference in the reason that individuals lacked complete coverage before the procedure (Table 4). For the CABG population by far the most common reason (58%) was due to the subject turning 65 years old in the 24 months before the procedure, whereas for the TMR population, nearly half lacked a full 24 months of coverage because their reason for coverage was disability and they got the disability coverage in the 24 months before the TMR. Despite this difference, the small number of subjects who lacked coverage overall suggests the chance from bias from this is small.

There is a difference in coverage following the procedure with the TMR alone group more likely to have incomplete coverage for the full 12 months (Table 3). The difference occurs within the first month and continues throughout the 12-month period following the procedure (Figure 2). This lack of coverage is almost exclusively (>99%) due to subject death in all groups. The effect of different rates of death between the groups was accounted for in subsequent analyses.

Creation of analytic variables

Demographic measures

The demographic measures used in the analysis included age, race and gender. Age was calculated as time from birth date (from Denominator file) to the date of surgery. Race and gender were extracted from Denominator files.

Comorbidity measure

An assessment of the comorbidity of the subjects is important for two reasons. First, a description of the comorbidities helps to characterize the cohorts. Second, as the comorbidities of individuals may account for a portion of the outcomes observed, statistical control of comorbidities may make the cohorts otherwise more comparable.

We assessed comorbidities using the Charlson comorbidity index.[4] This widely used scale has been validated for predicting mortality following hospitalizations. In the context that it is used here, it also partially assesses severity of coronary vascular disease in that it includes measures of the presence of a claim for a myocardial infarction. As we do not have other measures of severity that would allow us to otherwise distinguish severity and comorbidity, we elected to leave this diagnosis in the Charlson index. Therefore, in this case it is a measure primarily of comorbidity, but also partially of severity.

We examined all of the Inpatient and Carrier claims for the two years prior to the TMR and/or CABG procedure to identify comorbid conditions, including claims at the time of surgeries. The specific codes examined are listed in Appendix A. The list of comorbidity codes was adapted from Deyo et. al.[5] The average number of claims that went into the calculation of the Charlson score was slightly higher in the TMR population versus the CABG population. On average, 2.7 Inpatient claims and 57.3 Carrier claims were used to calculate the Charlson index for the TMR cohort, and on average 1.0 Inpatient claims and 41.7 Carrier claims for CABG cohort. Some difference in the Charlson index between the groups could be due to the difference in number of claims that were used in the calculation.

Pre-procedure utilization

Three measures of pre-procedure utilization were created: all hospitalizations, coronary heart disease (CHD) hospitalizations and physicians services for evaluation and management.

A “procedure date” for the procedure was established for every subject from the procedure date in Inpatient claims. For those matched, the difference between Inpatient procedure date and expense date in Carrier claims was small. For those Carrier claims with no matching Inpatient claims, Carrier expense date for surgery was used as “procedure date”. For patients who had more than one possibly qualifying procedure in the dataset (i.e., more than one TMR or CABG) the latest procedure was used. The Inpatient and Carrier claims for each individual for the twelve months prior to the procedure date were then examined and counted as discussed below. Claims for the procedure itself were excluded for prior to and post surgery hospitalization counting by comparing the admission date and discharge date.

For all measures based upon Inpatient claims, the claims were de-duplicated by admission and discharge dates to assure that there was only one claim per admission.

All hospitalization

Two variables were created for all hospitalization before the procedure: 1) presence of any hospitalization and 2) number of hospitalizations per person year. The presence of any hospitalization was considered positive if in the year before the procedure there was any claim in the Inpatient file for that individual with a discharge date within 365 days of the “procedure date” described above. The number of hospitalizations per person year was calculated by counting the number of de-duplicated Inpatient claims for each individual between the procedure date and 365 days before the procedure date. A hospitalization was included if its discharge date was within 365 days of the “procedure date”. This number was then multiplied by the coverage weight, calculated as the number of months of Part A FFS the individual had during the year prior to the procedure divided by 12. This resulted in the number of hospitalizations per person year for each individual. This was calculated to account for the differing number of months of coverage for individuals.

CHD hospitalization

Two variables were created for CHD hospitalization before the procedure: 1) presence of any CHD hospitalization and 2) number of CHD hospitalizations per person year. The presence of any CHD hospitalization was considered positive if in the year before the procedure there was any claim in the Inpatient file for that individual with a discharge date within 365 days of the “procedure date” described above which contained an ICD9 diagnosis code beginning with '410', '411', '412', '413', and '414' as primary diagnosis.

The number of CHD hospitalizations per person year was calculated by counting the number of de-duplicated CHD Inpatient claims for each individual between the procedure date and 365 days before the procedure date. A hospitalization was included if its discharge date was within 365 days of the “procedure date” and it contained an ICD9 diagnosis code beginning with '410', '411', '412', '413', and '414' as primary diagnosis. This number was then multiplied the coverage weight, calculated as the number of months of Part A FFS the individual had during the year prior to the procedure divided by 12. This resulted in the number of CHD hospitalizations per person year for each individual. This was calculated to account for the differing number of months of coverage for individuals.

Physician services

Because essentially all subjects had Carrier claims, only the number of claims per person-year was calculated rather than whether claims were present or not. The number of physicians’ services per person-year in Carrier claims was calculated by examining the Carrier claims for each individual for the year before the procedure. Claims with a date within 365 days of the “procedure date” were counted if they contained a BETOS code for “evaluation and management” in their line trailer. The specific codes are listed in Appendix B. Duplicate Carrier claims, based on HIC, procedure and expense date, were excluded before calculation. As was done with the hospitalization measures, the count result was multiplied by the coverage weight, calculated as the number of months of Part B FFS the individual had during the year prior to the procedure divided by 12, to arrive at a measure of claims per person year.

Outcome measurements:

Post procedure utilization

All hospitalization

Two variables were created for all hospitalization after the procedure: 1) presence of any hospitalization and 2) number of hospitalizations per person year. The presence of any hospitalization was considered positive if in the year after the procedure there was any claim in the Inpatient file for that individual with an admission date within 365 days of the “procedure date” described above. In order not to count transfers as readmissions, any admission within one day of the discharge date for the primary hospitalization (i.e., the hospitalization with the TMR or CABG that contained the “procedure date” for that individual) was excluded.

The number of hospitalizations per person-year was calculated by counting the number of de-duplicated Inpatient claims for each individual between the procedure date and 365 days after the procedure date. A hospitalization was included if its admission date was within 365 days of the “procedure date”, again excluding admissions within one day of discharge. This number was then multiplied the coverage weight, calculated as the number of months of Part A FFS the individual had during the year after the procedure divided by 12. This resulted in the number of hospitalizations per person year for each individual.

CHD hospitalization

Two variables were created for CHD hospitalization after the procedure: 1) presence of any CHD hospitalization and 2) number of CHD hospitalizations per person year. The presence of any CHD hospitalization was considered positive if in the year after the procedure there was any claim in the Inpatient file for that individual with a admission date within 365 days of the “procedure date” described above which contained an ICD9 diagnosis code of '410', '411', '412', '413', and '414' as primary diagnosis. As above, admissions within one day of the primary discharge date were excluded.

The number of CHD hospitalizations per person-year was calculated by counting the number of de-duplicated CHD Inpatient claims for each individual between the procedure date and 365 days after the procedure date. A hospitalization was included if its admission date was within 365 days of the “procedure date” and it contained an ICD9 diagnosis code beginning with '410', '411', '412', '413', and '414' as primary diagnosis. Again, admissions within one day of discharge were excluded. This number was then multiplied the coverage weight, calculated as the number of months of Part A FFS the individual had during the year after the procedure divided by 12. This resulted in the number of CHD hospitalizations per person year for each individual.

Physician services

Because essentially all subjects had Carrier claims, only the number of claims per person year was calculated rather than whether claims were present or not. The number of physician’s services per person year in Carrier claims was calculated by examining the Carrier claims for each individual for the year after the procedure. Claims with a date within 365 days of the “procedure date” were counted if they contained a BETOS code for “evaluation and management” in their line trailer. The specific codes are listed in appendix B. Duplicate Carrier claims based on HIC, procedure and date were excluded before calculation. The count result was multiplied the coverage weight, calculated as the number of months of Part B FFS the individual had during the year after the procedure divided by 12, to arrive at a measure of claims per person year.

To get an assessment of the use of physician services outside of the immediate postoperative period, an additional variable was calculated as above but excluding claims in the first thirty days following the TMR and/or CABG procedure.

Time to utilization of services

Time to rehospitalization was computed in the same manner as the assessment of presence of rehospitalization described above. For those individuals with a rehospitalization or a CHD rehospitalization, the time to rehospitalization was calculated as the difference between the discharge date for the primary (TMR or CABG as appropriate) hospitalization and the admission date of the rehospitalization. Again, readmissions within one day were excluded so as not to count transfers.

Mortality

Mortality information was obtained from the Denominator file. Data through March 31, 2003 was used for the mortality analysis as the files were updated to that date. Some of the death dates, however, were not validated for the extended period. For the unvalidated dates we used the end of month as the death date to be conservative in our analysis.

Analysis

All analysis was done using SAS version 8.2.

Geographic analysis

Beneficiary state and county codes were obtained from the Denominator files. The number of subjects in each county was counted, and this was mapped using the US county map in SAS. To obtain the location of the facility where the TMR was performed, the provider code in the Inpatient file was linked to the Place of Service (POS) Code from CMS (year 2002 version). These were counted within counties and mapped as described above. During the mapping process, both the beneficiary and provider state and county were changed from the SSA state and county code to the FIPS code to be consistent with the internal SAS coding system.

Percent who die and time to death

Whether a subject died was determined from the Denominator file. Unadjusted comparisons of the percent who died were done using a chi-squared test. Unadjusted time to death was done using Kaplan-Meier with censoring for the end of the study follow up. Adjusted time to death was estimated using baseline survival from the Cox proportional hazards models, holding adjustments at the population means. The adjustments included demographic characteristics (age, gender and race) as well as comorbidity (Charlson comorbidity score).

Percent with subsequent utilization and time to subsequent utilization

The percent of patients with subsequent utilization was tested using chi-squared testing. However, the percent with rehospitalization was complicated by the competing outcome of death. There is not a straightforward way of addressing this issue in the usual models of adjustment of a rate such as logistic regression. Because survival analysis can account for the censoring for other reasons in a straightforward manner, we examined the time to rehospitalization with Cox proportional hazards models as discussed for mortality above.

Numbers of utilization events per person year

Unadjusted means of the number of utilization events (rehospitalizations, CHD rehospitalizations, and physician services) were compared using t-tests. Adjusted analysis was examined using Generalized Linear Models. Because the numbers per person-year reflect different periods of observation for different subjects (as not everyone had a full year of coverage after the procedure, most frequently due to death), the regressions were weighted for the number of months of coverage after the procedure.

Results:

Overall the findings were similar for both the “Exact Match” and “All Possible” cohorts. Both sets of analyses are presented in the tables and figures. For consistency the “All Possible” cohort results will be discussed in the text except when any different conclusions would be drawn from the two cohorts. In this case both cohorts will be discussed.

Use of TMR and TMR+CABG

Using the estimates from the “All Possible” cohort, the overall number of TMR procedures done within the Medicare population numbered about 2000 nationally in both 2000 and 2001. About 73% of the TMR procedures done in 2000 were done in conjunction with a CABG (Figure 3). This increased to about 85% in 2001, largely due to a decrease in the number of TMR alone procedures from 559 to 286 between the two years; the rate of TMR in conjunction with CABG was relatively steady. Although the absolute numbers varied with cohort type (“Exact Match” or “All Possible”) the pattern between the years and between the TMR and TMR+CABG group did not.

The performance of TMR procedures was not concentrated in a few sites. Rather TMR procedures were performed in 221 counties across the nation in 2000 and 2001 (Figure 4). The sites that performed TMR drew from a widely scattered area. In 2000 and 2001 patients living in 1266 counties in the US underwent a TMR procedure (Figure 5). The geographic distribution of counties where the procedure was performed and counties of residence of the TMR patients was similar in 2000 and 2001 (not shown).

Demographic characteristics

Nearly a third of the population who received TMR alone was under age 65 (Table 5), which is over twice the percent in the Medicare population as a whole (13.4%). The reason for eligibility for Medicare for this under age 65 population was primarily disability, with a small percentage of patients (2-3%) with ESRD.

Approximately 17% of the patients who underwent TMR+CABG were under age 65, which is slightly higher than the 13.4% in the Medicare population as a whole. In contrast, about 9% of the CABG population was below age 65.

The age distribution of the TMR alone population (Figure 6) shows that the percent of patients in their fifties was about half of that of patients in their sixties. The distribution is more dramatic for the TMR+CABG and the CABG alone populations with a bigger change in the distribution at age 65.

All three of the TMR, TMR+CAGB, and CABG alone populations had a greater percentage of men than the Medicare population as a whole (72%, 70% and 65%, respectively, compared to 44% for the whole Medicare population). The percentage of the population that was white was also consistent across the populations at about 90%, which is greater than the 80% for the Medicare population as a whole.

Given the demographic differences between the TMR, TMR+CABG and CABG populations, statistical adjustment was made for these differences in comparing the outcomes that follow.

Comorbidity of the populations

The TMR and TMR+CABG populations had similar levels of comorbidity by the Charlson comorbidity index (Table 5). Both populations had a comorbidity score of approximately 4 (range 3.6 to 4, depending upon which year and cohort were examined) compared to a comorbidity score of 3.1 for the CABG alone population for both years. This greater average comorbidity score is not the result of a few outliers raising the overall average. Rather, the whole distribution is shifted uniformly upward for the TMR and TMR+CABG groups compared with the CABG alone group (Figure 7).

This difference in comorbidity between the groups could be due in part to artifact. As noted above, both the TMR and TMR+CABG populations had greater utilization in the year before the procedure, and as a result had on average a greater chance of existing comorbidities being noted in claims. That is, if one has no claims, the diagnoses that go into calculating the comorbidity index cannot be noted and counted. However, the differences in diagnoses that account for the differences in the Charlson comorbidity index make sense in a clinical context (Table 6). Most of the difference in the Charlson comorbidity index is the result of differences in the percent of patients who had a claim for a myocardial infarction, diabetes or peripheral vascular disease. This makes sense in a population who, by definition, has more severe coronary disease. The other diseases that one would expect should not be different between the groups such as chronic obstructive pulmonary disease, is little different between the groups, suggesting that the differences in comorbidity seen does reflect real differences between the groups of patients.

Mortality following the procedure

A greater percentage of the TMR alone patients died in the year following the procedure (19.2% for the “All Possible” population) compared to the TMR+CABG (12.5%) or CABG alone (10.9%) populations (Table 7). Although of lesser magnitude, the difference in first year mortality between the TMR+CABG and CABG alone populations was also statistically significant. The differences were similar regardless of whether one examined the patients with an “Exact Match” for TMR or the “All Possible” cohort.

Much of the difference in mortality happened early after the procedure (Figure 8) although the survival curve of the TMR alone population continued to diverge from the TMR+CABG and CABG alone populations throughout the 1000 days of maximum observation.

After adjustment for demographic differences, the TMR+CABG group was still statistically significantly different from the CABG alone group (Figure 9 and Table 8). In fact, the magnitude of the difference was greater. This is not unexpected given that the TMR+CABG group was younger overall than the CABG alone group and would therefore be expected to have a lower mortality rate. Adjusting for age, therefore, accentuated the mortality difference between the groups. The TMR alone group continued to have a significantly greater mortality than either the TMR+CABG or CABG alone groups after the adjustment for demographic characteristics.

After further adjustment for Charlson comorbidity score, the mortality difference between the TMR+CABG and CABG groups disappeared. (Figure 9 and Table 8) This suggests that the major driver of the difference in mortality between the groups was a difference in the health status of the patients rather than the outcome of the procedure itself.

The TMR alone group continued to have a statistically significantly greater mortality rate than the other two groups even after controlling for the Charlson index and demographic characteristics. As discussed above, we do not have a good measure of severity of cardiovascular disease and so cannot conclude whether the differences seen are due to poorer outcomes with the procedure or differences in severity of disease between the groups. That is, it is possible that patients with no bypassable lesions would do worse than those with bypassable lesions regardless of what intervention they had, if any. Since by definition, the TMR+CABG and the CABG alone groups had bypassable lesions, it may be the severity of cardiovascular disease and not the outcome of the procedure that accounts for the mortality differences observed.

Hospitalization following the procedure

Two types of hospitalization were examined in this study, all hospitalizations and hospitalizations related to coronary heart disease. We examined both the presence of a hospitalization as well as the number of hospitalizations in the year following the procedure.

All hospitalizations

The rate of hospitalization in the year before the procedure for the TMR alone cohort was nearly twice that of the CABG only cohort (68% vs. 34%). (Table 9) The group that underwent TMR+CABG had a rate closer to the CABG alone group (41% vs. 34%). In the year following the TMR, the rates were closer with about a 12% difference between the TMR alone group and the CABG group (55% vs. 43%). The rate of the TMR+CABG group was essentially the same as that of the CABG group. This narrowing gap was the result of a net decrease in the percent of patients with a hospitalization in the TMR alone group and a net increase in the CABG cohort.

One potential issue with the percent of patients rehospitalized is that patients who die can no longer be hospitalized. Therefore, one potential explanation for the decrease in the hospitalization rate (i.e., percent hospitalized) for the TMR alone cohort is that individuals were dying rather than being hospitalized. Therefore, what might be viewed as a positive outcome, that is, fewer hospitalizations, is really the result of a negative outcome, that is, greater death rate. To examine this, we examined time to rehospitalization because in the survival analysis, it is possible to censor individuals who have died and effectively examine the rate of rehospitalization excluding the effect of mortality.

In the examination of the time to rehospitalization, the TMR group continues to have a greater rate of rehospitalization than the TMR+CABG and CABG alone groups. (Figure 10) This difference persists even after controlling for demographic characteristics and the Charlson comorbidity score (Figure 11 and Table 10) although it is of a lesser magnitude. The hazard rate ratio for time to rehospitalization was 1.4 (with CABG as the reference) for TMR alone in the unadjusted analysis and dropped to 1.2 after full adjustment, but remained statistically significantly different. The time to rehospitalization for the TMR+CABG group remained statistically no different than the CABG alone group, even after adjustment.

The mean number of hospitalizations per person-year in the year following the procedure was examined in two ways: 1) the mean number of hospitalizations per person-year for the year after the procedure 2) the mean of the difference in the number of hospitalizations for each individual between the year prior to and year after the procedure.

The average TMR alone patient had the largest number of hospitalizations per person-year in the year following the procedure with an average of 1.98 per person-year (Table 11). This exceeded the 0.8 per person-year for the TMR+CABG cohort and 0.6 per person-year for the CABG alone cohort. The TMR+CABG number was also statistically significantly greater than the CABG alone group. After adjustment for demographics and the Charlson score, the TMR alone group still had the largest average number of hospitalizations per person-year of the three groups, but the TMR+CABG group was no longer greater than the CABG alone group.

Although the TMR alone group had the largest number of hospitalizations on average in the year following the procedure, it had the smallest change from the year before. This was due to the fact that the TMR group also had the greatest average number of hospitalizations in the year before the procedure. Whereas both the CABG group and the TMR+CABG group had an increase in the mean number of hospitalizations per person-year following the procedure, there was small decrease for the TMR group. For the TMR+CABG group the average increase was 0.30 hospitalizations per person-year when comparing the year before the procedure and the year following the procedure. For the CABG alone group, it was 0.41 hospitalizations per person-year. In both cases, the increase was statistically significant. These differences persisted after controlling for demographic characteristics and the Charlson comorbidity score.

The use of the number of hospitalizations per person-year (as opposed to not taking loss of coverage into account) only partially addresses the possibility that the number of hospitalizations in the TMR alone group may be smaller due to the higher mortality rate in the group and therefore the lessened opportunity for hospitalization. Depending upon the pattern of hospitalization before death, it is possible that the rate per person could be biased downward in the group with a higher mortality rate. To examine whether this accounts for the smaller increase in the mean number of hospitalizations per person-year in the TMR group compared to the TMR+CABG and CABG groups, we examined the mean number of hospitalizations only in those individuals who survived the full year after the procedure (Table 12). Again the same pattern is seen with the TMR alone group having the most positive response in the mean number of hospitalizations per person- year following the procedure. This suggests that this effect is not due to the greater mortality rate within this group.

CHD hospitalizations

As with the analysis of any hospitalization discussed above, a significantly greater percentage of the TMR alone population had a hospitalization for CHD in the year prior to the procedure as compared to either the CABG alone group (59% versus 16%) or the TMR+CABG group (59% versus 26%). (Table 9) Unlike the examination of all hospitalizations, these differences persisted after the procedure and were of equal or greater magnitude. In the year after the procedure, 30% of the TMR alone group had a hospitalization for CHD compared to 6% of the CABG group and 10% of the TMR+CABG group. Unlike the findings for all hospitalization where the percent of the TMR+CABG and CABG alone groups with a hospitalization was stable or increased following the procedure, all three groups showed a decrease in the percent with CHD hospitalization following the procedure.

Again, as discussed above, death may be a competing event for hospitalization. Hence, the analysis was performed examining the time to CHD hospitalization, which allows for censoring for death. Again the TMR group has a shorter time to rehospitalization than the TMR+CABG or CABG alone groups. (Figure 12) Unlike the findings for all hospitalizations, the TMR+CABG group had a statistically significantly greater hazard of CHD rehospitalization than did the CABG alone group, and this difference remained after controlling for demographics and the Charlson index. (Figure 13 and Table 13)

The pattern in the average number of CHD hospitalizations per person-year was similar to that of overall hospitalizations. Again, of the three groups, the TMR alone group had the greatest average number of CHD hospitalizations per person year in both the year before and the year after the procedure (Table 14), and the TMR+CABG group also exceeded the CABG alone group. Unlike the overall the observation for overall hospitalizations, individuals in all three groups had on average a decrease in the mean number of CHD hospitalizations per person year following the procedure, but again, the effect was greatest for the TMR alone group. This pattern was unchanged after adjustment for demographics and the Charlson score.

Use of physician services following the procedure

The use of physician services in the year before and year after the procedure was examined. Unlike the hospitalization analysis, where both the presence of any hospitalization and the mean number of hospitalizations per person year were examined, for physician services only the mean numbers were examined. As essentially all the individuals in the study had physician services, an analysis of the presence of physician services would not be fruitful.

The pattern of the utilization of physician services was similar to that which was found for overall hospitalizations. Again, in the year before the procedure, the TMR alone patients had on average more physician services than either the TMR+CABG or CABG alone populations did (Table 15). There was no difference between the latter two before adjustment; TMR+CABG had fewer physician services than TMR alone after adjustment. Similarly in the year after the procedure, the TMR alone population had the greatest number of physician services per person year. Because it is possible that the immediate post-procedure period might have different needs in terms of physician follow-up, we also examined the mean numbers excluding the first thirty days after the procedure and observed the same pattern of utilization between the groups.

Similar to what was seen for the hospitalizations following the procedure, the difference in the mean number of physician services per person-year was smaller for the TMR alone group than for the TMR+CABG group. Unlike the hospitalization findings, where the difference for the TMR alone group was also smaller than for the CABG alone group, for physician services the difference between the year before and the year after the procedure was essentially the same for the TMR alone group and the CABG alone group. This pattern was unchanged with adjustment for demographics and the Charlson score.

Summary and Discussion:

Summary of the findings

From this study a number of observations may be made about the use of TMR in the Medicare population and the outcomes and utilization following its use.

Use of TMR:

- The number of TMR procedures done was relatively stable between the years 2000 and 2001 although there was a decrease in the number of procedures done that did not accompany a CABG.
- TMR was done in a large number of institutions across the country rather than being concentrated in only a few.

Demographics and comorbidity of TMR population:

- Compared to the Medicare population as a whole, the population of patients getting TMR alone was on average younger and more likely to be: male, white, disabled. They were similar in gender and race to the Medicare population undergoing CABG.
- Compared to the Medicare population as a whole, the population of patients getting TMR+CABG was more likely to be: male, white, disabled. They were similar in gender and race to the Medicare population undergoing CABG.
- The TMR and TMR+CABG populations had a higher level of comorbidity than did the population undergoing CABG alone.

Mortality of TMR populations:

- The mortality rate in the year following the procedure was greatest for the patients who underwent TMR alone, followed by those who underwent TMR+CABG, and finally CABG alone. The difference between the TMR+CABG and CABG groups disappeared after controlling for comorbidities, suggesting that the comorbidities were driving the higher mortality rate in the TMR+CABG group.

Overall hospital utilization:

- Prior to the procedure, the TMR alone group had the highest overall hospital utilization, followed by the TMR+CABG group.

- In the year after the procedure, the TMR alone group still had higher overall hospital utilization than the TMR+CABG and CABG alone groups. The overall hospitalization rates of the TMR+CABG and CABG alone groups were similar.
- There was a small increase of overall hospitalizations after the procedure in the TMR+CABG and CABG alone groups, while the overall hospitalizations decreased slightly in the TMR alone group.

CHD specific hospital utilization

- Prior to the procedure, the TMR alone group had the highest CHD hospital utilization, followed by the TMR+CABG group.
- In the year after the procedure, the TMR alone group still had higher CHD hospital utilization than the TMR+CABG and CABG alone groups.
- CHD hospitalizations decreased in all three groups following the procedure. The greatest was in the TMR alone group, followed by the TMR+CABG and the CABG alone groups.

Physician services utilization

- Prior to the procedure, the TMR alone group had the highest level of utilization of physician services.
- In the year after the procedure, the TMR alone group still had higher utilization of physician services than the TMR+CABG and CABG alone groups.
- All groups had an increase in the utilization of physician services. The TMR+CABG group had the greatest increase.

Discussion:

In the two years following the approval of coverage for TMR, it remained a rather infrequent procedure within the Medicare population. There were less than one TMR alone procedure done within Medicare for every 4000 CABGs performed. Further less than 1% of CABGs had a TMR done in conjunction with it. There was not a significant increase between the two years; in fact the only real change in the utilization of TMR was a decrease in the use of TMR alone. Our findings suggest that this is not due to TMR being limited to a few centers and has simply not yet diffused geographically. Rather, there is a fairly wide geographic distribution and nowhere is it being done at a great rate.

Although the clinical trial findings would suggest that the TMR alone might be a more effective procedure than the TMR+CABG, it is perhaps not surprising that TMR+CABG still is the more common procedure within the Medicare population. The performance of TMR alone requires a thoracotomy specifically for the TMR procedure whereas TMR+CABG may be performed in the setting of a patient who is already undergoing a thoracotomy (i.e., for the CABG). The clinical barrier to performing TMR+CABG is therefore much less. It is also possible that there are more patients who would meet the indications for TMR+CABG than TMR alone, although we doubt this is a significant factor in the difference in utilization seen for the two procedures, as there are certainly far more Medicare patients who would meet the criteria for either TMR procedure than there are patients who received it. That is, it is unlikely that the small number of either procedure is affected by the number of potentially qualifying patients but rather on other factors such as whether physicians believe the procedure to be beneficial.

The higher level of comorbidity in the TMR groups compared to the CABG alone group makes sense given the role that diabetes plays in coronary artery disease. Diabetics are more likely to develop the severe diffuse disease that is not amenable to bypass for which TMR would then be indicated. This is exactly the pattern we see in these results with higher rates of diabetes in the two TMR cohorts. As we demonstrate in this study, this has important ramifications for the assessment of any study of TMR; if comorbidities are not taken into account, the outcomes of the TMR group may look worse due, not to the results of the procedure, but rather due to comorbid diseases.

The conclusions that can be drawn from these analyses are clearly limited by the lack of good comparisons. There is likely more overlap between the TMR+CABG group and the CABG alone group in that both groups met indications for CABG, and it is very likely that there are individuals in the CABG alone group that, clinically, in terms of the extent and severity of their heart disease and other comorbidities, are the same as individuals in the TMR+CABG group. It is harder to say this for the TMR alone group as by definition they did not have vessels amenable to bypass. Because of this, it is fairer to think of the results of the CABG comparison group as putting the other findings in context rather than as a metric by which to measure the other results.

The mortality rate within the group that received TMR alone was higher than that of the other two groups. CABG itself has a fairly modest effect on mortality; hence the greater mortality rate seen in the TMR alone group must arise either because the patients are sicker overall or because the TMR procedure is contributing to their mortality. Although we are not able to assess it directly in this study, we do know that they had more severe coronary artery disease on average as they had lesions that were not amenable to bypass. Clinical trials of TMR have not shown either survival benefit or harm from TMR alone compared to those treated medically. Frazier et. al.[1]found an 85% one year survival rate in the TMR patients and 79% in the medically treated patients (a non-significant difference). Further, Allen et. al.[2] found a 89% one year survival for those randomized to TMR and 84% for those randomized to medical therapy (a non-significant difference). These rates are similar to the 80.8% one year survival we found in the Medicare population in general undergoing TMR alone. These numbers suggest that when TMR is used in a general population, the mortality outcomes are similar to that seen in the clinical trials of TMR and the greater mortality seen in this population compared to those undergoing CABG relates to the worse medical status of this group.

We are able to draw more conclusions about mortality for the TMR+CABG population. Again, it is expected that they likely have more severe coronary artery disease on average as they too have regions of myocardium that are not amenable to bypass. Yet their overall mortality rate is, after accounting for their higher comorbidity, no worse than the group getting bypass alone suggesting that the TMR procedure did not contribute to mortality in this population.

The results from the utilization analysis may suggest that the TMR alone procedure may have beneficial results. Assuming that patients who are doing better clinically utilize fewer services, the smaller increases in utilization for the TMR alone group compared to the other groups for hospitalizations and physicians services suggests that these patients may be receiving benefit from the procedure. Yet it is not possible to exclude the possibility that other factors account for the apparent beneficial effects. Some possibly confounding factors include: 1) incomplete control for the effect of mortality, 2) that these individuals with end stage coronary disease are less likely to receive further care because there is little else to do for them, or 3) floor effects given the lower rates before the procedure for the other groups. Nonetheless, this finding suggests that TMR may have positive effects on utilization for this otherwise higher utilization group.

The findings from the TMR+CABG group overall seem reassuring. The changes in utilization is comparable to the CABG alone group suggesting that the TMR did not do harm; whether it provided benefit cannot be ascertained. The one exception to this pattern is the findings for physician services in which the TMR+CABG group seemed to do a little worse than the other groups in terms of changes following the procedure. Whether this is the result of unmeasured severity or comorbidity or harm from the procedure is not clear.

Analysis of claims data is at a disadvantage compared to clinical trials when examining TMR outcomes such as symptoms and functional status. Yet unlike clinical trials, analysis of claims data is able to give us a broad picture of the use of TMR and its effect on mortality and utilization. Although this broad but limited examination may not allow firm conclusions, it can raise flags where outcomes are not what would be expected from the clinical trials. We identified no such flags. Within the limits of these analyses, we found nothing that suggests that TMR and TMR with CABG when applied to the general Medicare population results in outcomes different than those seen in the clinical trials of the procedures.

Tables

Table 1: Matching of Inpatient and Carrier claims for TMR and TMR+CABG for 2000-2001

		Claim identified in Carrier file					
		TMR	TMR+ CABG	CABG	33999[†]	33999[†]+ CABG	Neither TMR nor CABG
Claim identified in Inpatient file	TMR	628	72	4	8	13	119
	TMR+CABG	4	1633	236	0	405	200
	CABG	5	320	2	1	1	6
	Neither TMR nor CABG	95	161	11			

[†] HCPCS code 33999 was used nonspecifically for TMR prior to assignment of HCPCS code for TMR

Table 2: Numbers of subjects in each analytic cohort in 2000 and 2001

	2000	2001	Total	Percent of total patients
Exact match cohort				
TMR	436	200	636	16.2%
TMR+CABG	988	1050	2038	51.9%
All possible match cohort				
TMR	559	286	845	21.5%
TMR+CABG	1504	1559	3063	78.1%
TMR patients included in the analysis	2063	1845	3908	
Excluded patients			16	0.4%
Total TMR patients			3924	
20% CABG sample	36963	34886	71849	

Table 3: Percent of patients in each cohort who had at least 24 months pre surgery coverage, and at least 12 months post surgery coverage by type of coverage (Part A and Part B FFS)

	Part A before surgery	Part A after surgery	Part B before surgery	Part B after surgery
Exact match				
TMR	84.1%	79.9%*	82.9%	79.6%*
TMR + CABG	84.8%	87.6%	83.2%	87.5%
All possible				
TMR	82.4%	79.3%*	79.9%	77.2%*
TMR + CABG	83.6%	86.5%	80.9%	84.6%
CABG	84.8%	88.0%	82.0%	86.0%

* p <0.01 for TMR vs. CABG

Table 4: Reasons for less than 24 months of fee for service coverage before surgery as percent of total with incomplete coverage

	Exact match		All possible		
	TMR	TMR+CABG	TMR	TMR+CABG	CABG
Part A					
Medicare status					
Age < 65 only (OASI)	41.9%* #	54.1%	36.5%	55.0%	58.2%
ESRD	3.2%	2.4%	4.4%	1.9%	3.1%
Disabled only	46.2%* #	20.6% #	48.9%* #	21.6% #	12.8%
HMO	3.3%	4.0%	3.4%	3.8%	4.1%
Part B					
Medicare status					
Age < 65 only (OASI)	40.6%* #	51.1%	34.2%* #	50.2%	52.1%
ESRD	3.0%	2.4%	3.8%	1.8%	2.9%
Disabled only	45.5%* #	20.8% #	50.6%* #	22.2% #	13.2%
HMO	3.3%	4.0%	3.4%	3.8%	4.1%

"Age<65 only" means individuals had coverage at the time of the procedure because they were over age 65 and turned 65 in the 24 months prior to the procedure. "ESRD" and "Disabled only" means the individuals had coverage at the time of the procedure because of ESRD or disability and gained that coverage in the 24 months before the procedure. "HMO" includes those who were in an HMO for part of the 24 months before the procedure or had other reasons for not having coverage.

The groups are not mutually exclusive

*: $p < 0.01$ for TMR vs. TMR+CABG
#: $p < 0.01$ for TMR vs. CABG or TMR+CABG vs. CABG

Table 5: Demographic characteristics and comorbidity of the cohorts in 2000, 2001 and overall

Exact match cohort

	2000		2001		Total	
	TMR	TMR+CABG	TMR	TMR+CABG	TMR	TMR+CABG
N	436	988	200	1050	636	2038
%<65	30.3 * #	17.9 #	31.0 * #	16.7 #	30.5 * #	17.3 #
%male	72.2 #	69.2	72.5	70.2	72.3 #	69.7 #
%white	92.4	89.9	90.0	89.2	91.7	89.6
%black	4.4 * #	5.9 #	7.0 * #	5.9 #	5.2 * #	5.9 #
%Disabled	28.9% * #	16.6 #	29.5 * #	15.8 #	29.1 * #	16.2 #
%ESRD	2.5 * #	1.4 #	3.5 * #	2.3	2.8 * #	1.9 #
Age mean(SD)	67.2 (9.8)	69.9 (8.3)	68.2 (10.0)	70.1 (8.5)	67.5 (9.9)	70.0 (8.4)
Charlson score mean(SD)	4.0 (2.3)	3.7 (2.5)	4.4 (2.6)	3.9 (2.6)	4.1 (2.4)	3.8 (2.6)

All possible cohort

	2000		2001		Total	
	TMR	TMR+CABG	TMR	TMR+CABG	TMR	TMR+CABG
N	559	1504	286	2559	845	3063
%<65	32.7 *#	17.4#	33.9 *#	17.4 #	33.1 *#	17.4 #
%male	71.9 #	68.9 #	71.3	70.5 #	71.7 #	69.7 #
%white	91.6	88.8	88.8	90.0	90.7	89.4
%black	5.4	5.9 #	7.0 *#	5.2	5.9 #	5.6 #
%Disabled	31.1 *#	16.2 #	32.2 *#	10.0 #	31.5 *#	12.3 #
%ESRD	2.3	2.3	3.1 *#	1.4 #	2.6 *#	1.7 #
Age mean(SD)	66.6 (9.8) *#	69.7 (8.3) #	67.5 (9.8) *#	69.8 (8.7) #	66.9 (9.8) *#	69.8 (8.5) #
Charlson score mean(SD)	3.8 (2.4) #	3.6 (2.5) #	4.2 (2.6) *#	3.8 (2.5) #	4.0 (2.5) *#	3.7 (2.5) #

CABG cohort

	2000	2001	Total
N	36963	34886	71849
%<65	8.8	8.9	8.8
%male	64.4	65.5	64.9
%white	91.5	91.1	91.3
%black	5.0	5.3	5.1
%Disabled	7.8	8.1	7.9
%ESRD	2.3	2.3	2.2
Age mean(SD)	72.4 (7.4)	72.3 (7.6)	72.3 (7.5)
Charlson score mean(SD)	3.1 (2.3)	3.1 (2.3)	3.1 (2.3)

For same year comparison, *: p<0.01 for TMR vs. TMR+CABG;
# p<0.01 for TMR vs. CABG or TMR+CABG vs. CABG

Table 6: Percent of TMR, TMR+CABG, and CABG patients with specific comorbidities for all possible and CABG cohorts

	2000			2001		
Charlson diagnosis	TMR alone	TMR+CABG	CABG	TMR alone	TMR+CABG	CABG
Myocardial infarction	62.8% *#	56.6% #	48.8%	67.1% *#	55.9% #	47.7%
Diabetes without complications	55.1% #	53.1% #	39.6%	57.0% *#	54.1% #	39.9%
Chronic heart failure	56.2% *#	45.9% #	39.5%	59.8% *#	42.7% #	38.2%
Chronic pulmonary disease	39.4% *	34.9%	36.8%	42.3% *#	36.4%	36.8%
Cerebrovascular disease	35.4% *#	43.8% #	34.8%	38.8% *#	45.5% #	35.6%
Peripheral vascular disease	31.1% *#	23.7% #	21.4%	35.0% *#	28.3% #	22.1%
Neoplasm excluding skin cancer	10.4% *#	12.1% #	14.8%	11.9%	13.6% #	14.7%
Diabetes with chronic complications	22.0% *#	18.9% #	11.8%	23.4% *#	20.5% #	12.2%
Chronic renal failure	9.8% *#	8.5% #	6.8%	9.8% #	9.5% #	6.9%
Peptic ulcer disease	8.1% *#	5.2% #	6.5%	10.1% *#	6.2% #	5.6%
Rheumatologic disease	3.4% *#	3.9% #	4.9%	5.2% *#	3.9% #	4.6%
Hemiplegia or paraplegia	1.1% *#	1.8% #	1.5%	2.8% *#	1.5%	1.6%
Metastatic solid tumor	0.4% *#	1.4%	1.4%	1.4%	1.3%	1.3%
Dementia	0.9%	0.8%	0.9%	0.3% *#	1.2% #	0.9%
Mild liver disease	0.7%	0.5%	0.7%	0.3% *#	0.8% #	0.6%
Moderate to severe liver disease	0.0% *#	0.4%	0.3%	0.0% *#	0.3%	0.2%
HIV or AIDS	0.0%	0.1%	0.1%	0.3% #	0.3% #	0.1%

For same year comparison, *: p<0.01 for TMR vs. TMR+CABG;
#: P<0.01 for TMR vs. CABG or TMR+CABG vs. CABG

Table 7: Mortality rates within a year following TMR, TMR+CABG, and CABG

		2000			2001			Total	
	Pop	Death	Rate	Pop	Death	Rate	Pop	Death	Rate
Exact match									
TMR	436	82	18.8% * #	200	43	21.5% * #	636	125	19.7% * #
TMR+CABG	988	117	11.8% #	1050	121	11.5% #	2038	238	11.7% #
All possible									
TMR	559	104	18.6% * #	286	60	21.0% * #	854	164	19.2% * #
TMR+CABG	1504	193	12.8% #	1559	191	12.3% #	3063	384	12.5% #
CABG	36963	4111	11.1% $	34886	3700	10.6%	71849	7811	10.9%

For same year comparison, *: p<0.01 for TMR vs. TMR+CABG;
#: p<0.01 for TMR vs. CABG or TMR+CABG vs. CABG

$: p<0.01 for Year 2000 vs. Year 2001

Table 8: Hazard rate ratio for mortality: unadjusted, adjusted for demographic characteristics, and adjusted for demographic characteristics and Charlson comorbidity

		Unadjusted			Adjusted for demographics			Full model		
		RR	95% confidence limits		RR	95% confidence limits		RR	95% confidence limits	
Exact match										
	TMR	1.99	1.73	2.30	2.37	2.06	2.74	1.97	1.71	2.27
	TMR+CABG	1.09	0.98	1.21	1.18	1.06	1.31	1.02	0.91	1.14
All possible										
	TMR	1.97	1.73	2.23	2.40	2.12	2.73	2.01	1.78	2.28
	TMR+CABG	1.14	1.04	1.24	1.24	1.14	1.35	1.10	1.01	1.20
Reference	CABG	1			1			1		

Note: 95% confidence limits not covering 1.0 is equivalent to p<0.05.

Table 9: Percent and (number) of subjects with a hospitalization (any hospitalization and CHD hospitalization) in the year before and after TMR, TMR+CABG, and CABG

Cohort	All hospitalization rate (n)		CHD hospitalization rate (n)	
	Pre-procedure	Post procedure	Pre-procedure	Post procedure
Exact match				
TMR	68.2% (434)	55.2% (351)	58.6% (373)	29.7% (189)
TMR+CABG	41.3% (842)	44.3% (903)	26.1% (532)	9.9% (201)
All possible				
TMR	66.9% (565)	52.7% (445)	58.1% (491)	28.6% (242)
TMR+CABG	42.2% (1292)	43.9% (1345)	27.2% (837)	9.9% (304)
CABG	34.0% (24411)	42.5% (30543)	16.2% (11637)	5.7% (4091)

Note:95% confidence limits not covering 1.0 is equivalent to $p<0.05$.

Table 10: Hazard ratios for rehospitalization for TMR, TMR+CABG, CABG, unadjusted, and adjusted for demographics, comorbidities, and baseline rate(pre-hospitalization), for exact match and all possible match

		Unadjusted			Adjusted for demographics		
		RR	95% confidence limits		RR	95% confidence limits	
Exact match							
	TMR	1.44	1.30	1.60	1.51	1.36	1.68
	TMR+CABG	1.04	0.97	1.11	1.06	1.00	1.14
All possible							
	TMR	1.35	1.23	1.48	1.41	1.29	1.55
	TMR+CABG	1.03	0.98	1.09	1.05	1.00	1.11
Reference	CABG	1			1		

		Adjusted for demographics and Charlson score			Adjusted for demographics, Charlson score and pre-hospitalization rate		
		RR	95% confidence limits		RR	95% confidence limits	
Exact match							
	TMR	1.33	1.20	1.48	1.24	1.12	1.38
	TMR+CABG	0.97	0.91	1.04	0.96	0.90	1.03
All possible							
	TMR	1.27	1.15	1.39	1.18	1.08	1.30
	TMR+CABG	0.97	0.92	1.03	0.96	0.91	1.02
Reference	CABG	1			1		

Note: 95% confidence limits not covering 1.0 is equivalent to $p<0.05$.

Table 11: Average number (standard deviation) of hospitalization per person-year within a year before and after TMR, TMR+CABG, and CABG, and the difference of pre-post hospitalization numbers, unadjusted and adjusted for demographics and comorbidities

			Unadjusted			Adjusted for demographics, Charlson score		
		N	Pre-Procedure	Post-procedure	Post-pre difference	Pre-Procedure	Post-procedure	Post-pre difference
Exact match								
	TMR	636	1.98 (2.35)*#	1.84 (2.96) *#	-0.15 (3.13)*#	1.79 (1.26) *#	1.69 (2.02) *#	-0.10 (2.02)
	TMR+CABG	2038	0.82 (1.48) #	1.12 (2.05)	0.30 (2.28)	0.71 (1.35) #	1.03 (1.81)	0.32 (2.26)
All possible								
	TMR	845	1.98 (2.47)*#	1.73 (2.82) *#	-0.25 (3.09)*#	1.80 (1.16) *#	1.61 (2.03) *#	-0.19 (2.03)*#
	TMR+CABG	3063	0.88 (1.55) #	1.13 (2.05) #	0.24 (2.27) #	0.78 (1.11)#	1.04 (1.66)	0.27 (2.21) #
Reference	CABG	71849	0.61 (1.19)	1.02 (1.94)	0.41 (2.08)	0.62 (1.07)	1.02 (1.87)	0.41 (2.14)

For same year comparison, *: p<0.01 for TMR vs. TMR+CABG;
#: p<0.01 for TMR vs. CABG or TMR+CABG vs. CABG

Table 12: Among individuals who survived at least one year after the procedure: Average number of hospitalization per person-year within a year before and after TMR, TMR+CABG, and CABG, and the difference of pre-post hospitalization numbers, unadjusted and adjusted for demographics and comorbidities

			Unadjusted			Adjusted for demographics, Charlson score
		N	Pre-Procedure	Post-procedure	Post-pre difference	Post-pre difference
Exact match						
	TMR	511	1.93 (2.34) *#	1.56 (2.17) *#	-0.38 (2.35) *#	-0.34 (1.58) *#
	TMR+CABG	1800	0.77 (1.38) #	0.95 (1.49) #	0.18 (1.80) #	0.20 (1.70) #
All possible						
	TMR	681	1.96 (2.48) *#	1.51 (2.11) *#	-0.45 (2.44) *#	-0.41 (1.57) *#
	TMR+CABG	2678	0.81 (1.43) #	0.98 (1.57) #	0.17 (1.83) #	0.18 (1.55) #
Reference	CABG	64010	0.57 (1.14)	0.84 (1.38)	0.26 (1.58)	0.26 (1.52)

For same year comparison, *: p<0.01 for TMR vs. TMR+CABG;
#: p<0.01 for TMR vs. CABG or TMR+CABG vs. CABG

Table 13: Hazard ratios for CHD rehospitalization for TMR, TMR+CABG, CABG, unadjusted, and adjusted for demographics, comorbidities, and baseline rate(pre-hospitalization), for "Exact match" and "All possible"

		Unadjusted			Adjusted for demographics		
		RR	95% confidence limits		RR	95% confidence limits	
Exact match							
	TMR	5.94	5.13	6.87	5.22	4.51	6.06
	TMR+CABG	1.77	1.54	2.04	1.67	1.45	1.93
All possible							
	TMR	5.71	5.02	6.51	4.93	4.32	5.62
	TMR+CABG	1.78	1.59	2.00	1.67	1.48	1.87
Reference	CABG	1			1		

		Adjusted for demographics and Charlson score			Adjusted for demographics, Charlson score and pre-hospitalization rate		
		RR	95% confidence limits		RR	95% confidence limits	
Exact match							
	TMR	4.95	4.27	5.75	3.97	3.42	4.62
	TMR+CABG	1.61	1.40	1.86	1.54	1.33	1.77
All possible							
	TMR	4.72	4.13	5.38	3.79	3.31	4.34
	TMR+CABG	1.62	1.44	1.82	1.53	1.36	1.72
Reference	CABG	1			1		

Note: 95% confidence limits not covering 1.0 is equivalent to $p<0.05$.

Table 14: Average number (standard deviation) of CHD hospitalization per person-year within a year before and after TMR, TMR+CABG, and CABG, and the difference of pre-post hospitalization numbers, unadjusted and adjusted for demographics and comorbidities

			Unadjusted		
		N	Pre Procedure	Post procedure	Post-pre difference
Exact match					
	TMR	636	1.33 (1.74) *#	0.65 (1.57) *#	-0.69 (2.03) *#
	TMR+CABG	2038	0.45 (1.03) #	0.15 (0.54) #	-0.30 (1.09) #
All possible					
	TMR	845	1.34 (1.89) *#	0.62 (1.57) *#	-0.72 (2.10) *#
	TMR+CABG	3063	0.49 (1.09) #	0.16 (0.59) #	-0.32 (1.15) #
Reference	CABG	71849	0.24 (0.72)	0.09 (0.46)	-0.15 (0.82)

			Adjusted for demographics, Charlson score		
		N	Pre-Procedure	Post-procedure	Post-pre difference
Exact match					
	TMR	636	1.27 (0.76) *#	0.63 (0.50) *#	-0.64 (0.76) *#
	TMR+CABG	2038	0.41 (0.90) #	0.14 (0.45)	-0.27 (0.90)
All possible					
	TMR	845	1.28 (0.87) *#	0.60 (0.58) *#	-0.68 (0.87) *#
	TMR+CABG	3063	0.45 (0.55) #	0.15 (0.55) #	-0.30 (1.11) #
Reference	CABG	71849	0.24 (0.80)	0.09 (0.54)	-0.16 (0.80)

For same year comparison, *: p<0.01 for TMR vs. TMR+CABG;
#: p<0.01 for TMR vs. CABG or TMR+CABG vs. CABG

Table 15: Average number (standard deviation) of physician services (E&M) in the year before and after TMR, TMR+CABG, and CABG (exact match and all possible), and difference of pre-post physician services, unadjusted, and adjusted for demographics, comorbidities

			Unadjusted			
		N	Pre-procedure	Post procedure	Post procedure excluding first 30days	Post-pre difference excluding first 30 days
Exact match						
	TMR	636	20.90 (22.31) *#	28.98 (41.56) #	27.13 (37.02) #	4.54 (34.77)
	TMR+CABG	2038	14.08 (16.20)	25.25 (37.66)	23.48 (34.22) #	8.68 (34.50) #
All possible						
	TMR	845	20.38 (22.54) *#	29.97 (48.39) #	26.24 (37.33) #	4.91 (35.90) *
	TMR+CABG	3063	14.41 (16.38)	27.33 (44.48) #	24.22 (39.02) #	9.72 (39.32) #
Reference	CABG	71849	14.32 (14.65)	23.47 (40.62)	18.79 (34.23)	4.39 (35.48)

			Adjusted for demographics, Charlson score			
		N	Pre-procedure	Post procedure	Post procedure excluding first 30days	Post-pre difference excluding first 30 days
Exact match						
	TMR	636	18.88 (13.87) *#	27.83 # (39.59)	25.57 # (35.05)	5.28 (37.32)
	TMR+CABG	2038	12.87 (13.99) #	24.27 (34.30)	22.28 (34.31)	8.92 # (36.57)
All possible						
	TMR	845	18.64 (13.95) *#	29.40 # (35.46)	25.36 # (35.46)	5.85 * (39.37)
	TMR+CABG	3063	13.29 (13.84) #	26.53 # (40.40)	23.34 # (34.87)	10.01 # (37.63)
Reference	CABG	71849	14.38 (13.40)	23.52 (40.21)	18.84 (29.49)	4.37 (37.52)

For same year comparison, *: p<0.01 for TMR vs. TMR+CABG,
#: p<0.01 for TMR vs. CABG or TMR+CABG vs. CABG

Figures

Figure 1
Identification of cohorts from matching process (explanation of Table 1)
Black or gray fill represents a cell used in that cohort

Exact match (TMR (gray) and TMR+CABG (black) groups)

		Claim identified in Carrier file					
		TMR	TMR+ CABG	CABG	33999	33999+ CABG	Neither TMR nor CABG
Claim identified in Inpatient file	TMR						
	TMR+CABG						
	CABG						
	Neither TMR nor CABG						

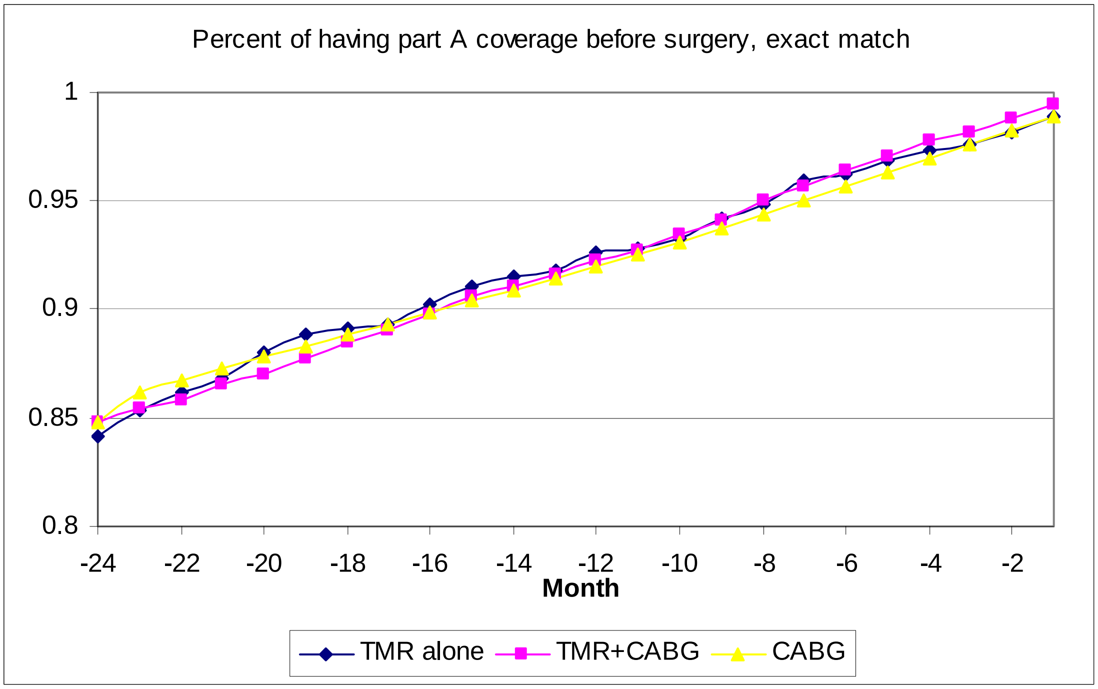
All possible (TMR group)

		Claim identified in Carrier file					
		TMR	TMR+ CABG	CABG	33999	33999+ CABG	Neither TMR nor CABG
Claim identified in Inpatient file	TMR						
	TMR+CABG						
	CABG						
	Neither TMR nor CABG						

All possible (TMR+CABG group)

		Claim identified in Carrier file					
		TMR	TMR+ CABG	CABG	33999	33999+ CABG	Neither TMR nor CABG
Claim identified in Inpatient file	TMR						
	TMR+CABG						
	CABG						
	Neither TMR nor CABG						

Figure 2: Percent of cohort having Part A FFS by months before and after procedure



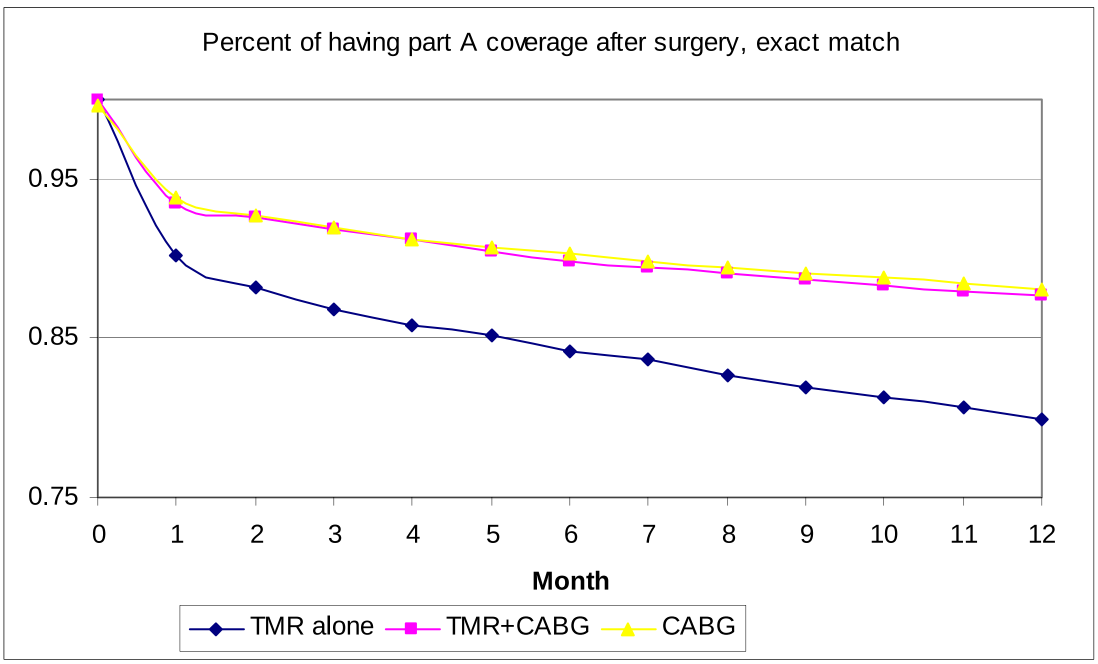


Figure 3: Number of individuals within the Medicare population receiving TMR alone and TMR+CABG in 2000 and 2001: Identification by Exact match or All possible

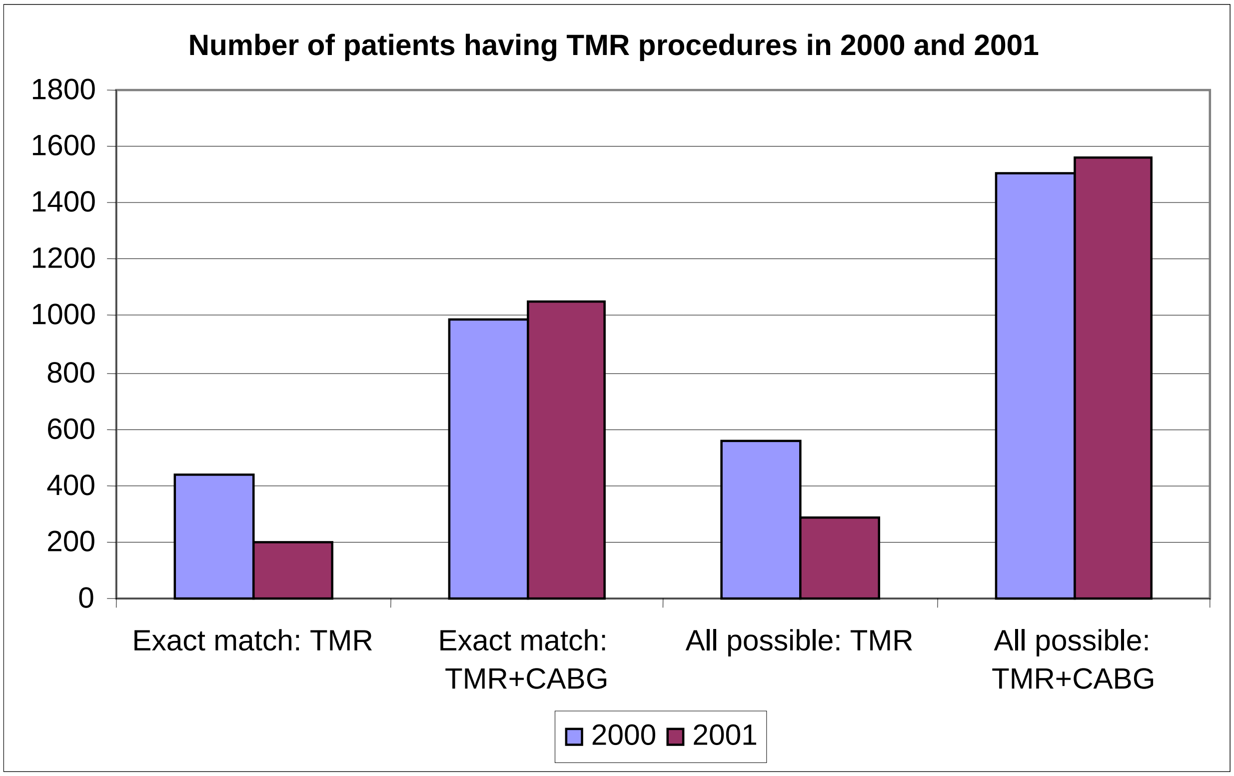


Figure 4: Number of TMR and TMR + CABG procedures performed in each US county in 2000 and 2001, by location of hospital, for "All Possible" cohort

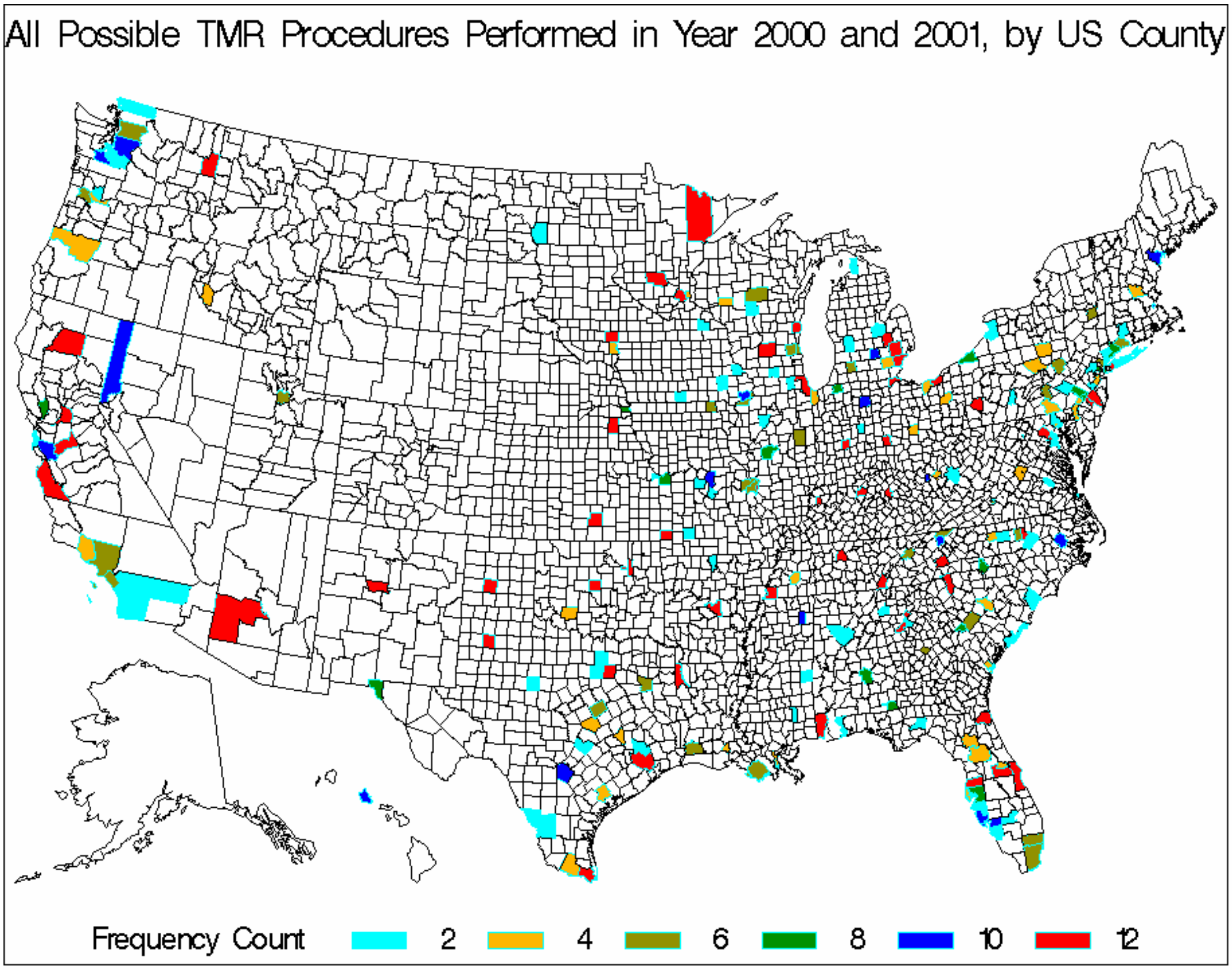


Figure 5: Number of Medicare beneficiaries living in each US county who underwent TMR or TMR with CABG procedures in 2000 and 2001 (“All Possible” cohort)

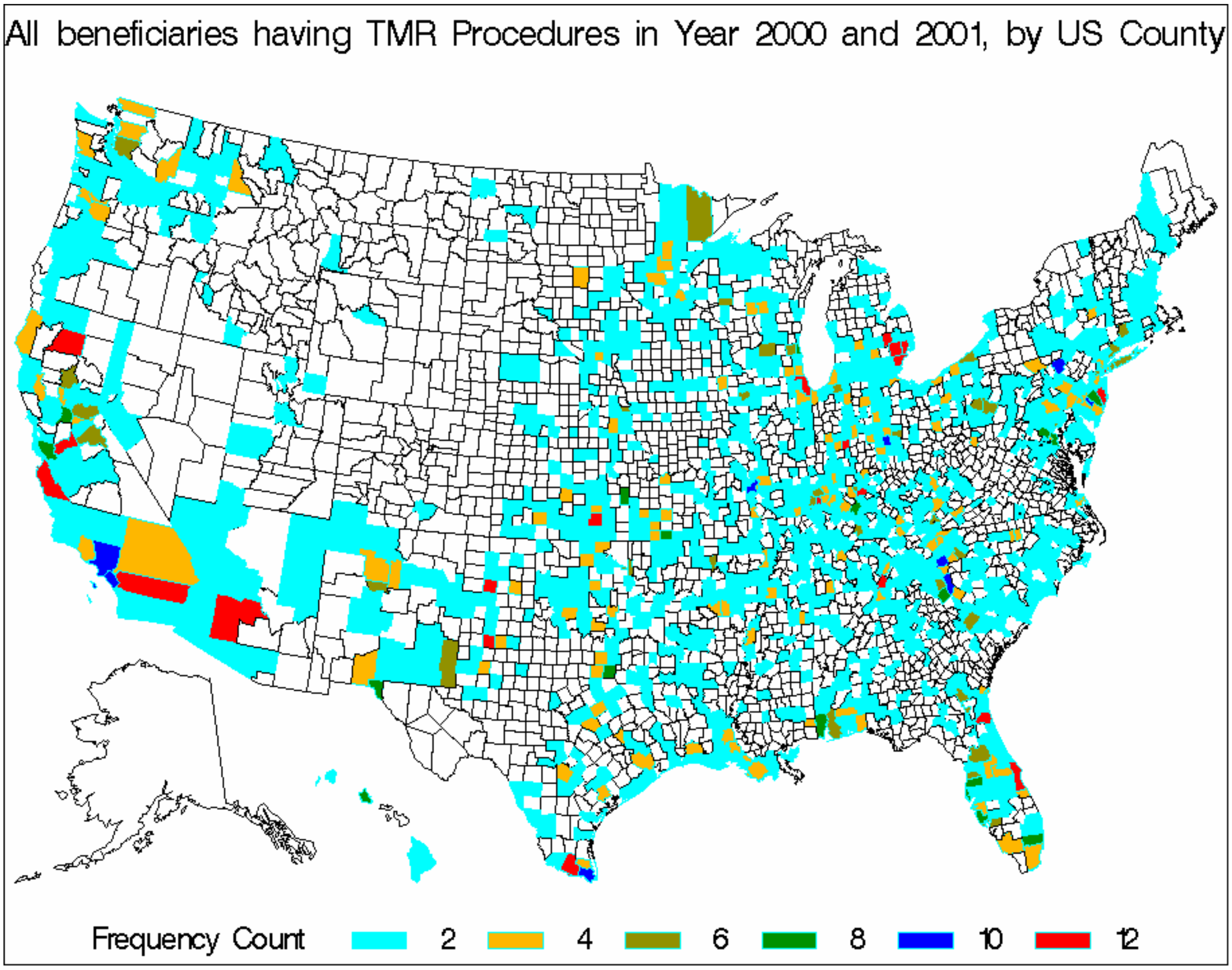


Figure 6: Age distribution of TMR, TMR+ CABG and CABG alone populations

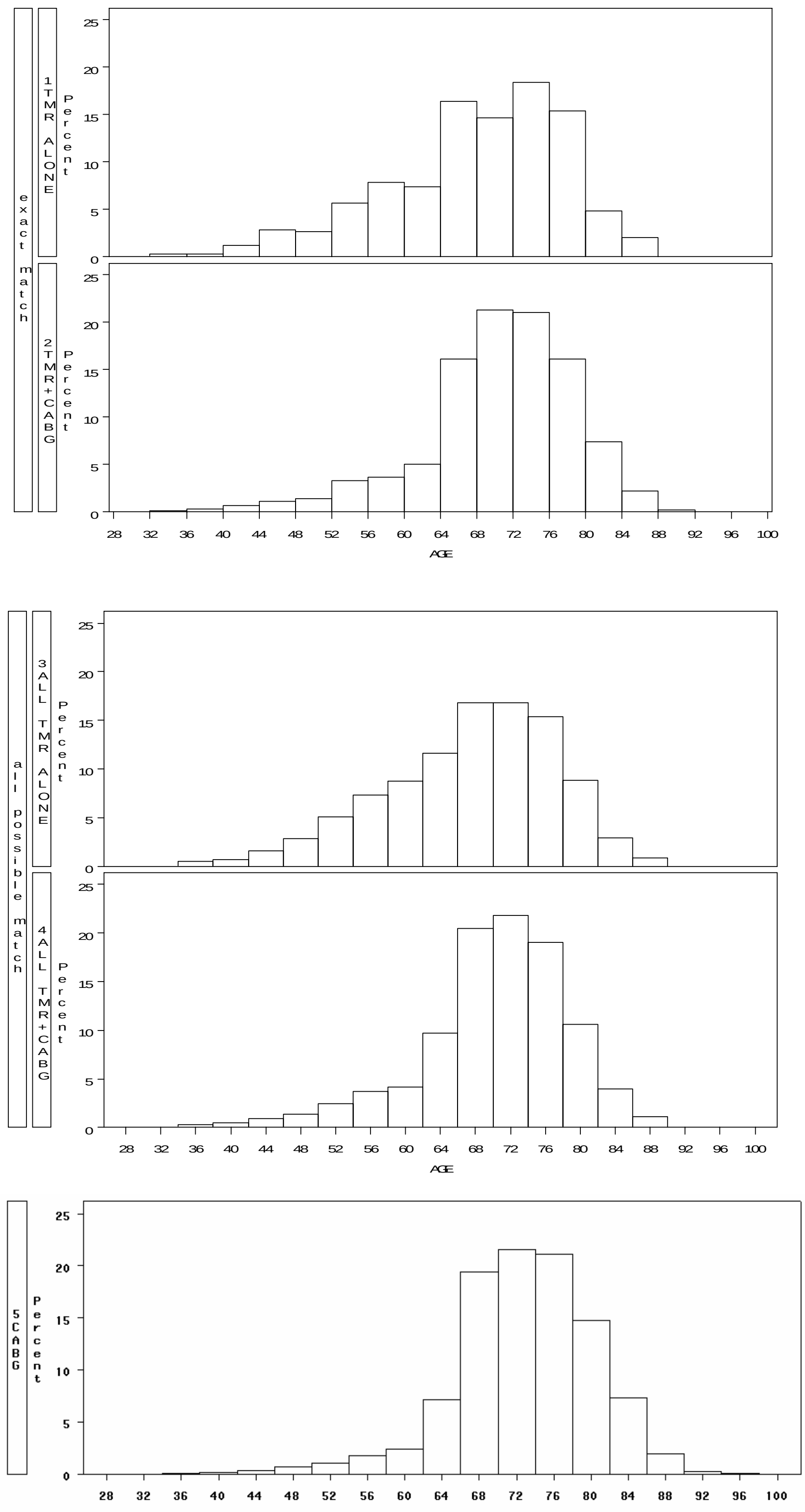


Figure 7: Distribution of Charlson comorbidity scores for the TMR, TMR+CABG and CABG populations

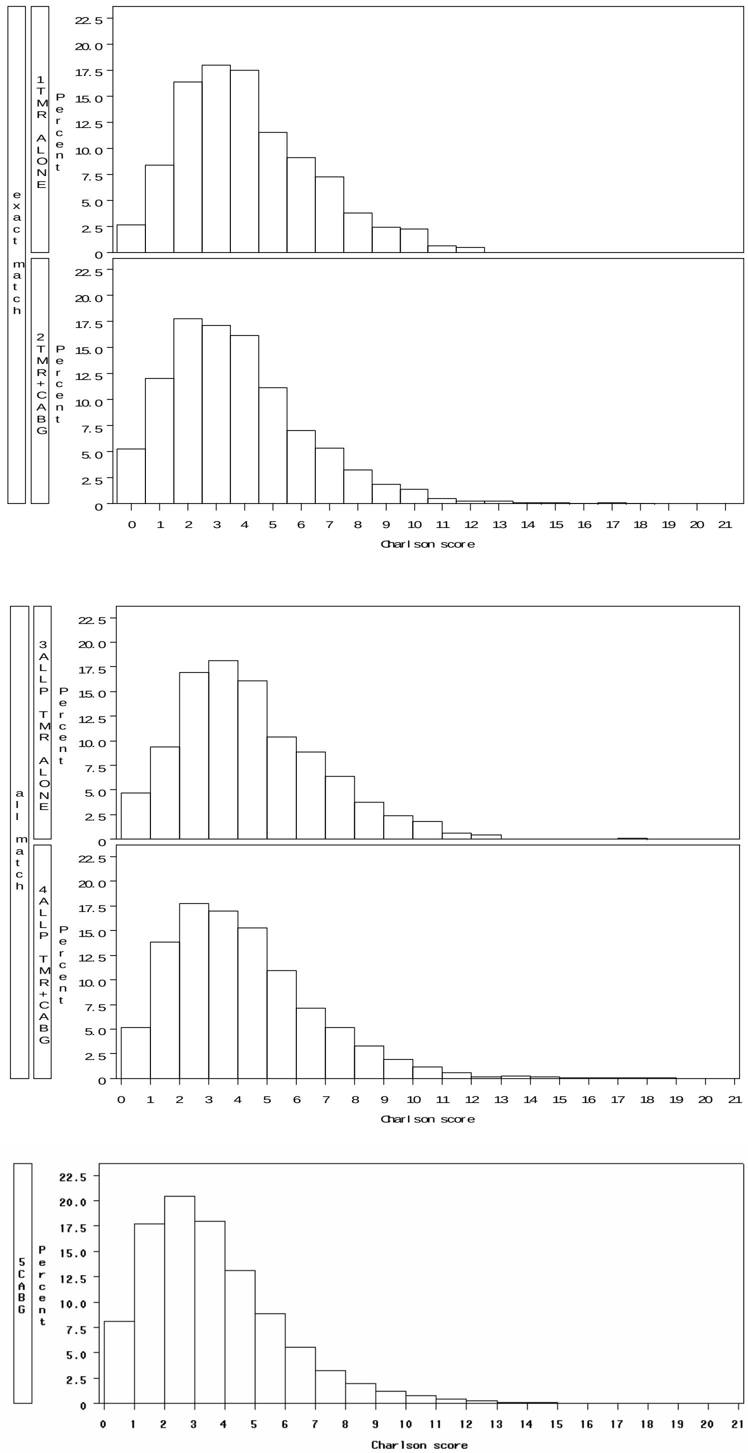
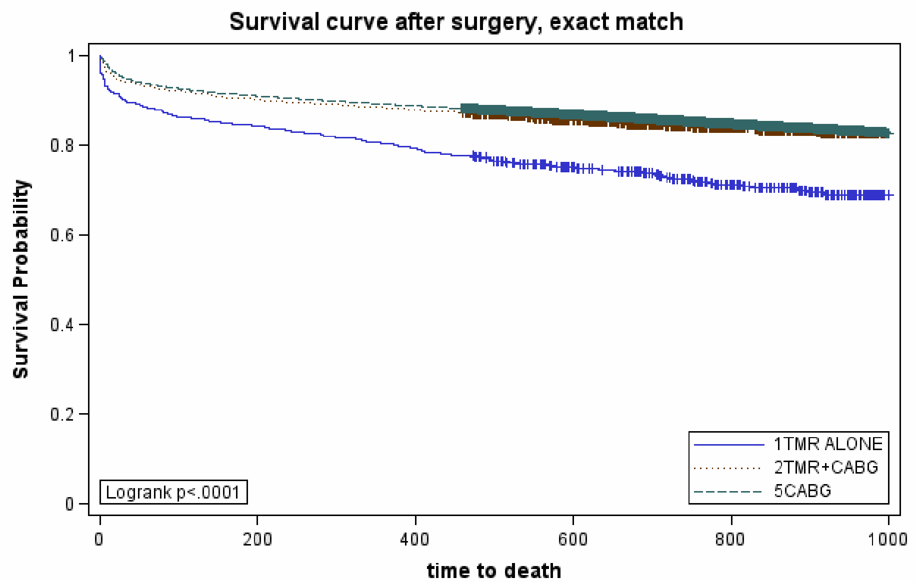
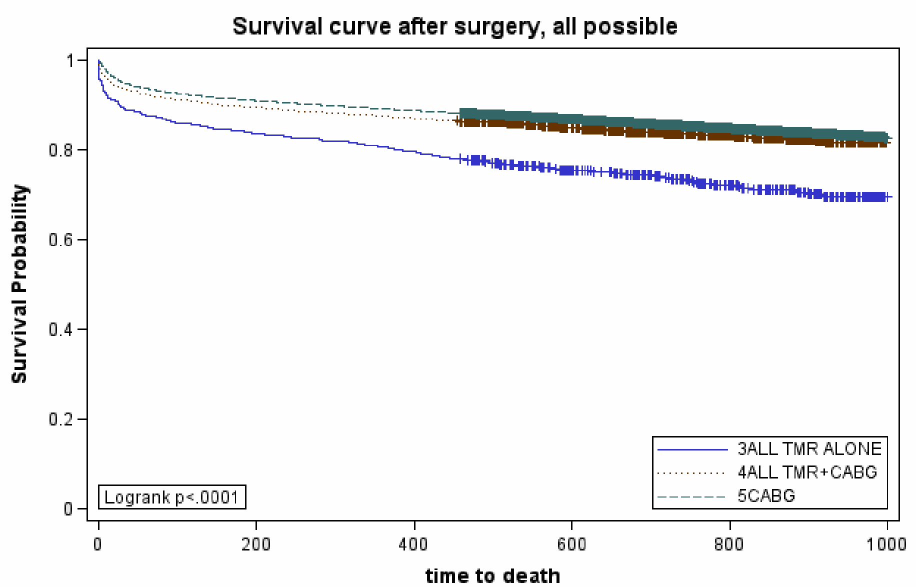


Figure 8: Kaplan-Meier survival curve following surgery

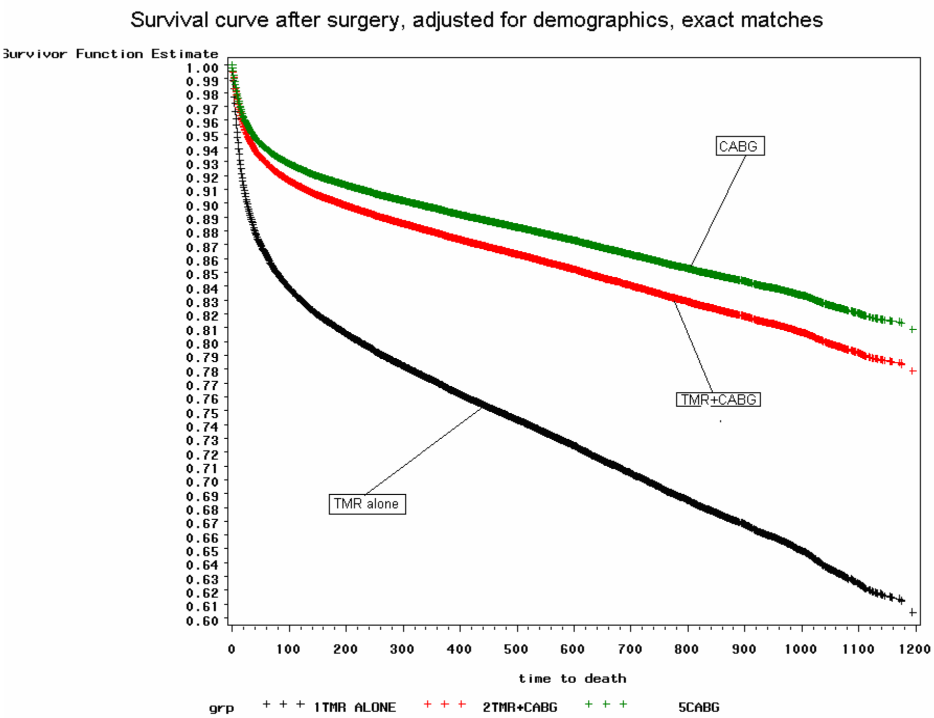


	No. of Subjects	Event	Censored
1TMR ALONE	636	30% (191)	70% (445)
2TMR+CABG	2038	17% (340)	83% (1698)
5CABG	71846	16% (11214)	84% (60632)



	No. of Subjects	Event	Censored
3ALL TMR ALONE	845	29% (249)	71% (596)
4ALL TMR+CABG	3063	17% (531)	83% (2532)
5CABG	71846	16% (11214)	84% (60632)

Figure 9: Adjusted survival curve (mortality), exact matches and all possible



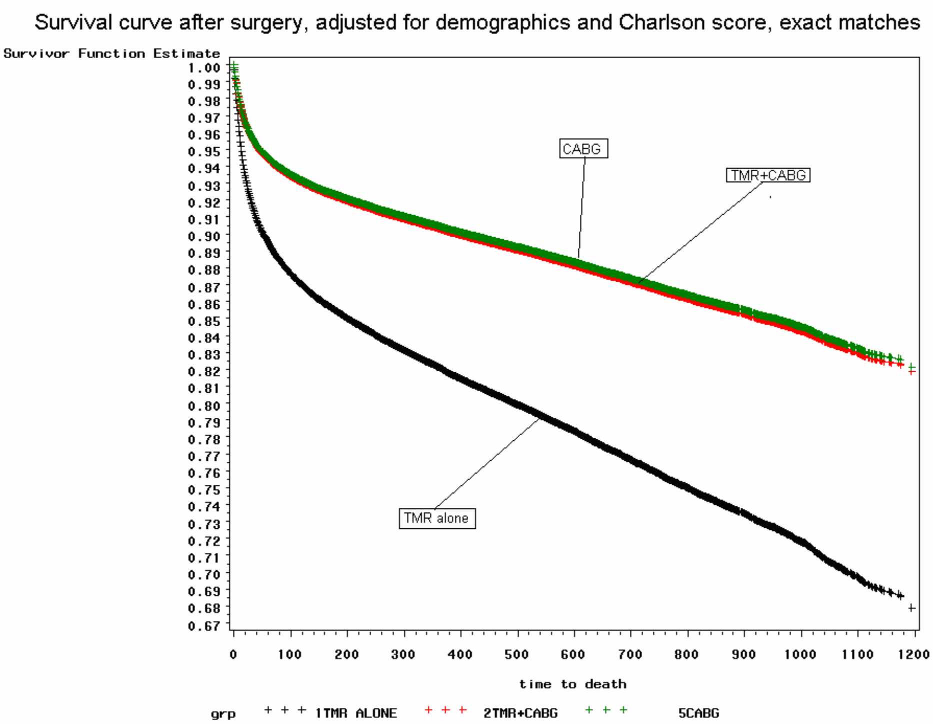
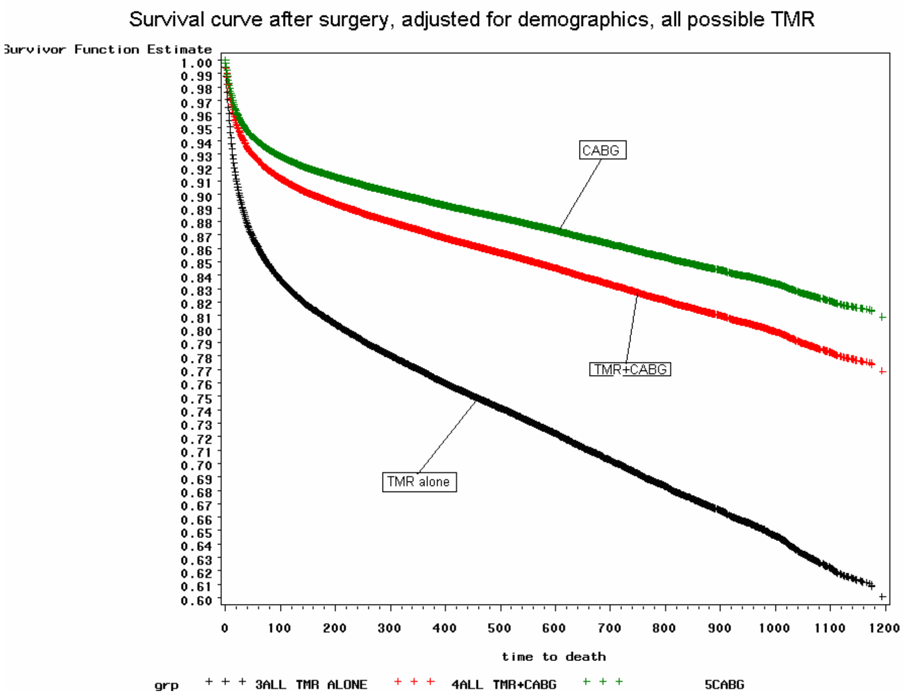


Figure 9: continue



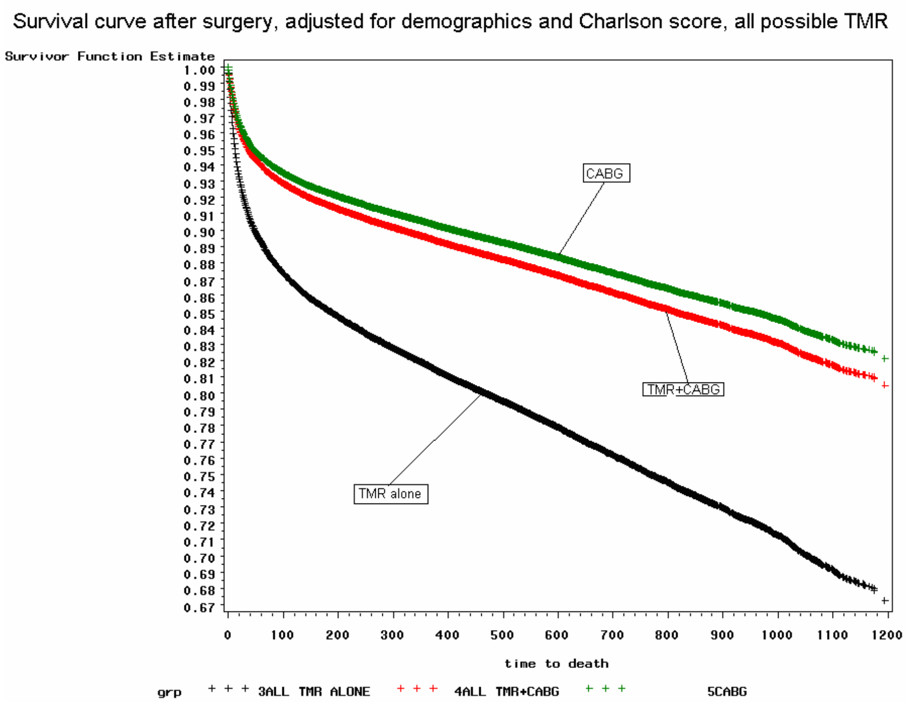
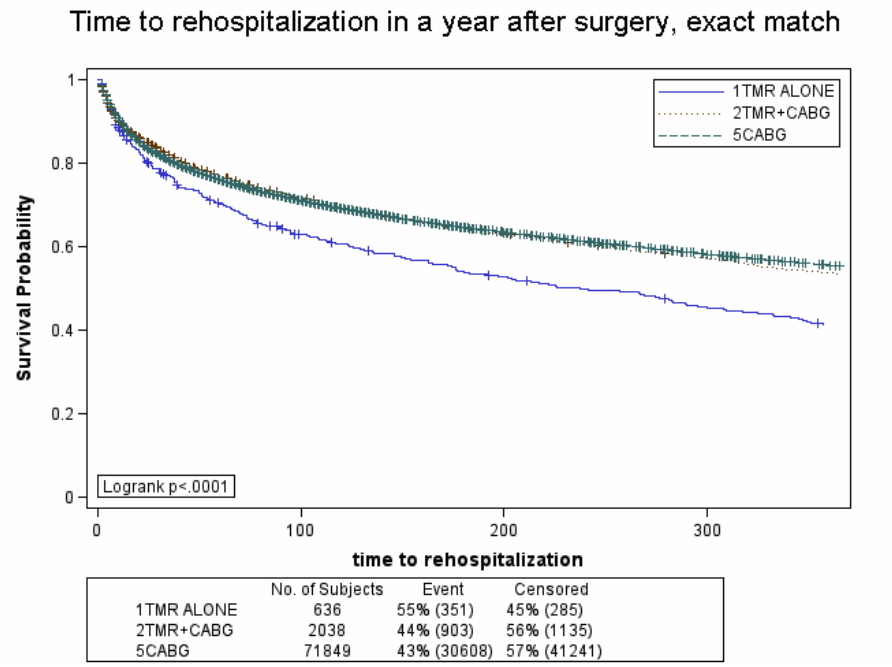


Figure 10: Time to rehospitalization following procedure, unadjusted



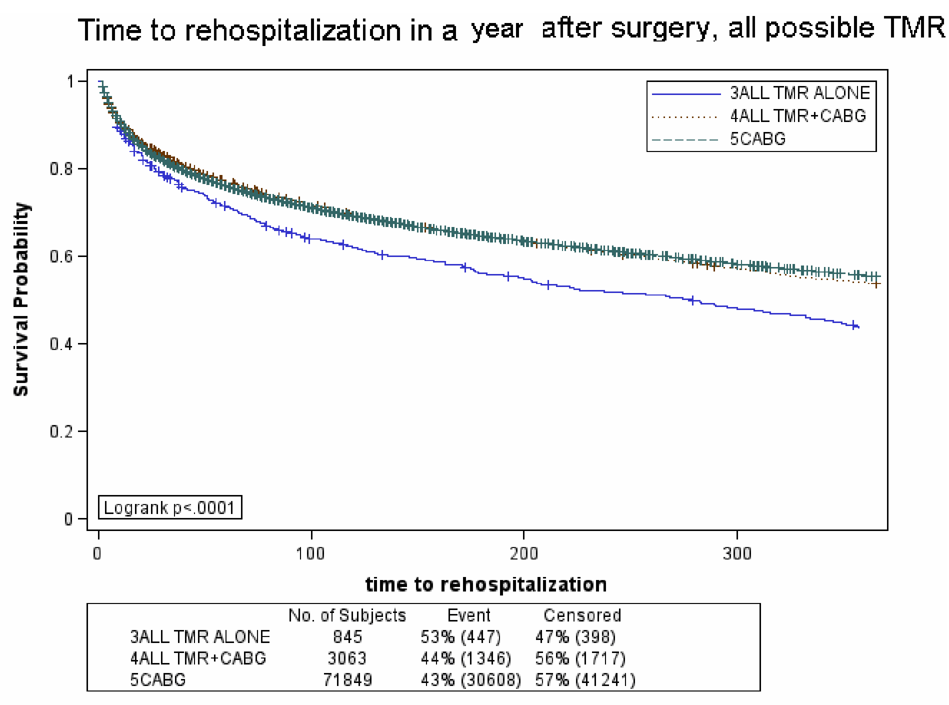
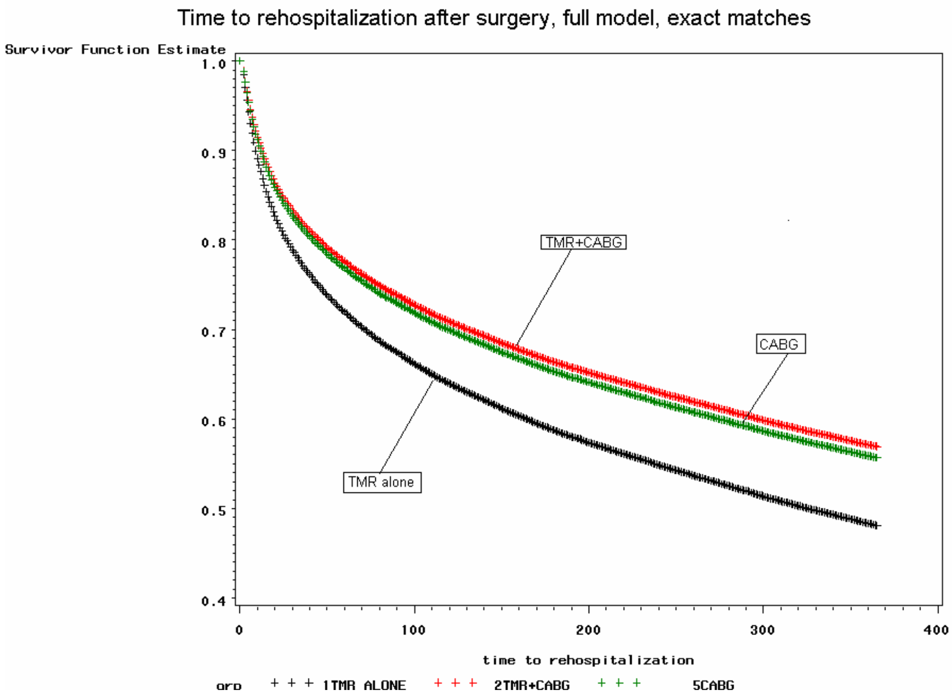


Figure 11: Time to rehospitalization, adjusted for demographics and Charlson comorobidity



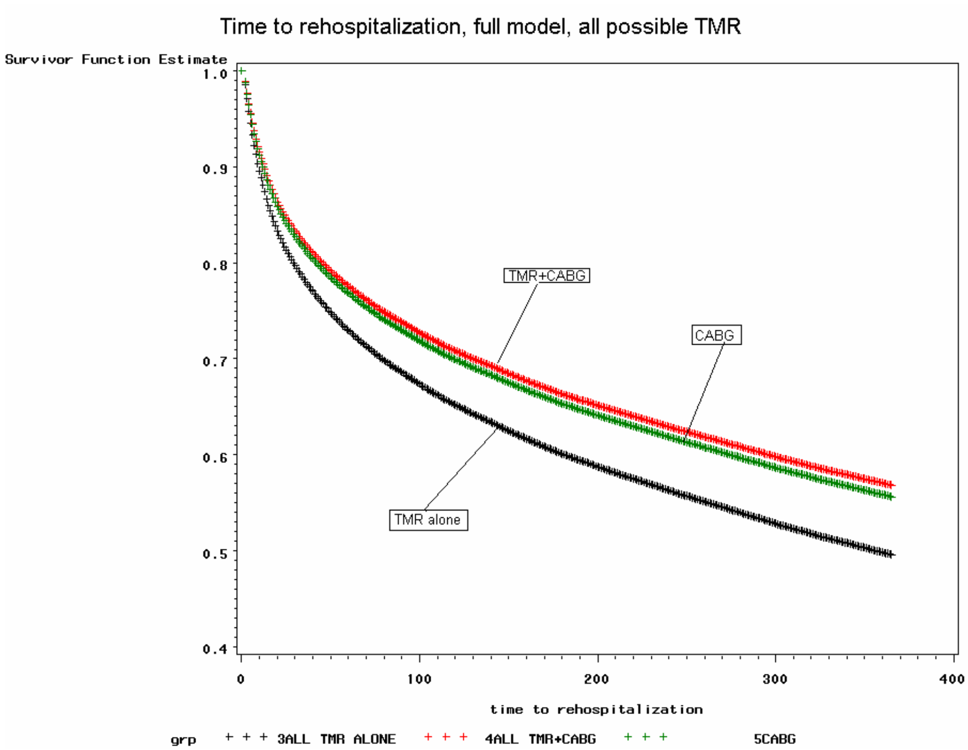
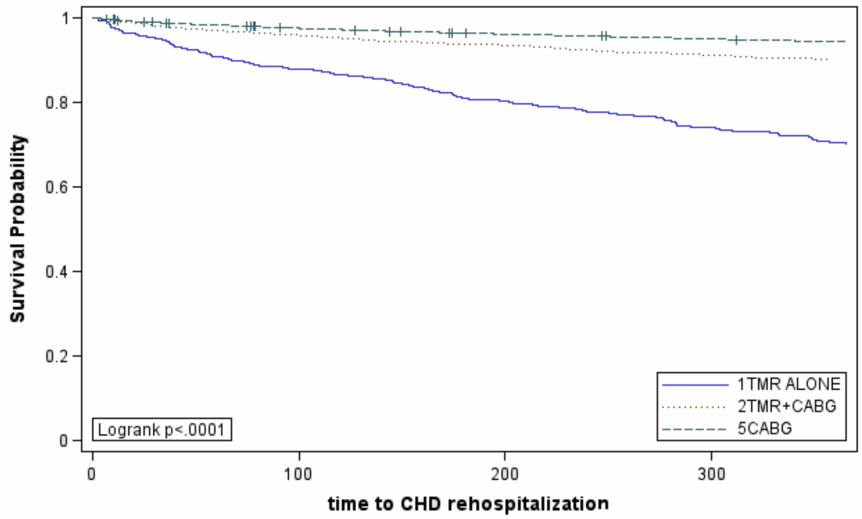


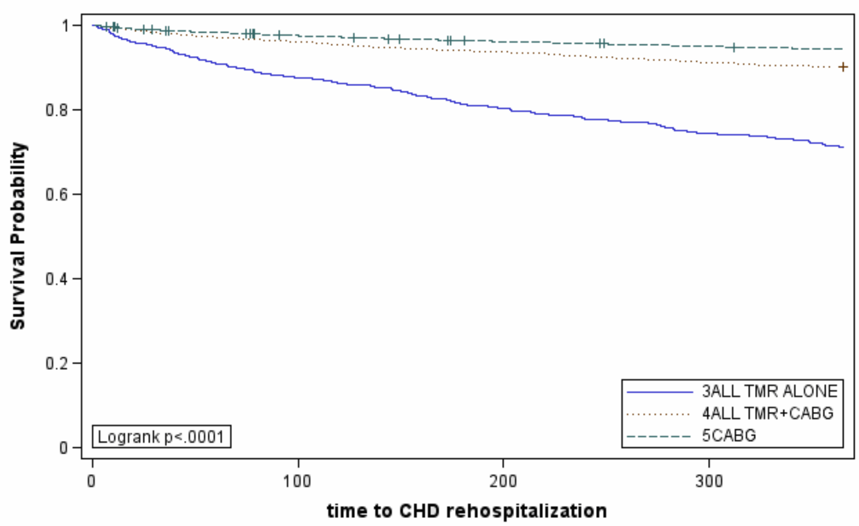
Figure 12: Time to CHD rehospitalization following procedure, unadjusted

Time to CHD rehospitalization in a year after surgery, exact matches



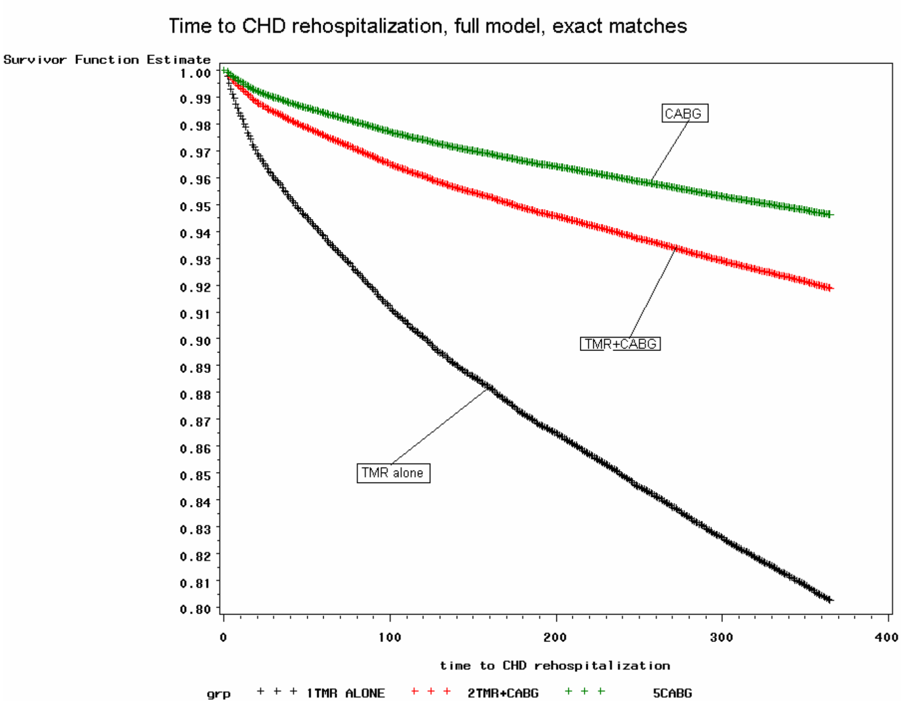
	No. of Subjects	Event	Censored
1TMR ALONE	636	30% (189)	70% (447)
2TMR+CABG	2038	10% (201)	90% (1837)
5CABG	71849	6% (4101)	94% (67748)

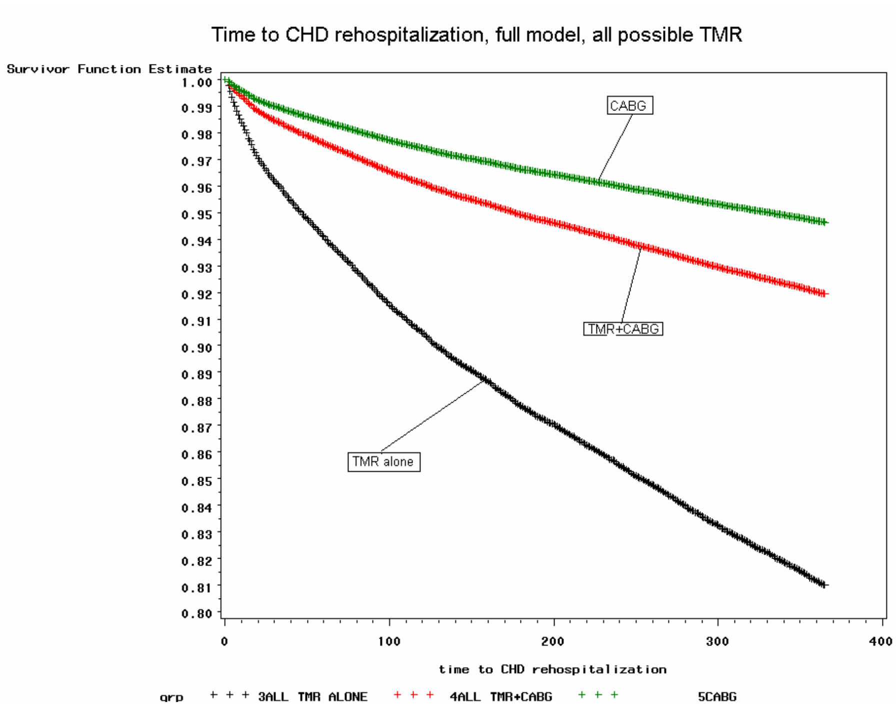
Time to CHD rehospitalization in a year after surgery, all possible TMR



	No. of Subjects	Event	Censored
3ALL TMR ALONE	845	29% (244)	71% (601)
4ALL TMR+CABG	3063	10% (304)	90% (2759)
5CABG	71849	6% (4101)	94% (67748)

Figure 13: Time to CHD rehospitalization following procedure, adjusted for demographics and Charlson comorbidity





Appendix

Appendix A

ICD-9-CM Codes used in calculating the Charlson Comorbidity index from Deyo et. al.[5] and specific SAS code used

Diagnostic category	ICD-9-CM	Weight
Chronic pulmonary disease	490.x-496.x, 500.x-505.x, 506.4	1
Diabetes without complications	250.0-250.3, 250.7	1
Diabetes with chronic complications	250.4-250.6	2
HIV or AIDS	042.x-044.9	6
Mild liver disease	571.2, 571.5, 571.6, 571.4-571.49	1
Any malignancy excluding skin cancer	140.x-172.9, 174.x-195.8, 200.x-208.9	2
Hemiplegia or paraplegia	344.1, 342.x-342.9	2
Dementia	290.0-290.9	1
Rheumatologic disease	710.0, 710.1, 710.4, 714.0-714.2, 714.81, 725	1
Peptic ulcer disease	531.x-534.9, 531.4-531.7, 532.4-532.7, 533.4-533.7, 534.4-534.7	1
Chronic renal failure	582.0-582.9, 583.0-583.7, 585.x, 586.x, 588-588.9	2
Peripheral vascular disease	443.9, 441-441.9,785.4, V43.4, procedure 38.48	1
Moderate or severe liver disease	572.2-572.8, 456.0-456.21	3
Metastatic solid tumor	196.x-199.1	6
Cerebrovascular disease	430.x-438.x	1
Congestive heart failure	428.0-428.9	1
Myocardial infarction	410.0-410.9, 412.x	1

* Charlson score were computed by searching above codes among both Inpatient and Carrier claims at the time of surgery and two year before the surgery, weighted by weights in the above table

```
SAS Macro:

%MACRO CHARLSON (ICD9DX);
ICD9DX3=SUBSTR(LEFT(&ICD9DX),1,3);
ICD9DX4=SUBSTR(LEFT(&ICD9DX),1,4);
ICD9DX5=LEFT(&ICD9DX);
      *** THESE THREE USED TO SHORTEN THE RUN TIME;

IF ICD9DX3 IN ('490' '491' '492' '493' '494' '495' '496'
      '500' '501' '502' '503' '504' '505')
      OR ICD9DX4='5064'
      THEN COPD=1;  * CHRONIC PULMONARY DISEASE;
IF ICD9DX4 IN ('2500' '2501' '2502' '2503' '2507')
      THEN DIAB=1; * DIABETES WITHOUT COMPLICATIONS;
```

```
IF ICD9DX4 IN ('2504' '2505' '2506')
      THEN DMWCC=1; * DIABETES WITH CHRONIC COMPLICATIONS;
IF ICD9DX3 IN ('042' '043' '044')
      THEN HIV=1; *HIV AND AIDS;
IF ICD9DX4 IN ('5712' '5715' '5716' '5714')
      THEN MLDLD=1; * MILD LIVER DISEASE;
IF ICD9DX3 IN ('140' '141' '142' '143' '144' '145' '146' '147'
   '148' '149' '150' '151' '152' '153' '154' '155' '156' '157' '158'
   '159' '160' '161' '162' '163' '164' '165' '170' '171' '172' '174'
   '175' '176' '177' '178' '179' '180' '181' '182' '183' '184' '185'
   '186' '187' '188' '189' '190' '191' '192' '193' '194' '195' '200'
   '201' '202' '203' '204' '205' '206' '207' '208')
      THEN NEOPLAS=1; * ANY MALIGANANCY, INCLUDING LEUKEMIA AND LYMPHOMA,
                        EXLUDING SKIN CANCER(173);
IF ICD9DX3 = '342' OR ICD9DX4='3441'
      THEN HEMIPL=1;  * HEMIPLEGIA OR PARAPLEGIA;
IF ICD9DX3 = '290' THEN DEMENT=1; * DEMENTIA;
IF ICD9DX4 IN ('7100' '7101' '7104' '7140' '7141' '7142')
      OR ICD9DX5='71481'
      OR ICD9DX3='725'
      THEN RHEUM=1; * RHEUMATOLIGIC DISEASE;
IF ICD9DX3 IN ('531' '532' '533' '534')
      THEN PUD=1; * PEPTIC ULCER DISEASE;
IF ICD9DX3 IN ('582' '585' '586' '588')
      OR ICD9DX4 IN ('5830' '5831' '5832' '5833' '5834' '5835' '5836' '5837')
      THEN CRF=1; * CHRONIC RENAL FAILURE;
IF ICD9DX3 = '441' OR ICD9DX4 IN ('4439' '7854' 'V434')
      THEN PVD=1; * PERIPHERAL VASCULAR DISEASE;
      *** BY ARLENE: THEY ALSO INCLUDED A PROCEDURE FOR PVD OF '3848';
      *** WE CHOSE NOT TO INCLUDE THE PROCEDURE CODES;

IF ICD9DX4 IN ('5722' '5723' '5724' '5725' '5726' '5727' '5728'
      '4560' '4561')
      OR ICD9DX5 IN ('45620' '45621')
      THEN MSLD=1; * MODERATE OR SEVERE LIVER DISEASE;
IF ICD9DX3 IN ('196' '197' '198')
      OR ICD9DX4 IN ('1990' '1991')
      THEN METS=1; * METASTATIC SOLID TUMOR;
IF  ICD9DX3 IN ('430' '431' '432' '433' '434' '435' '436' '437' '438')
      THEN CEVD=1; * CEREBROVASCULAR DISEASE;
IF ICD9DX3 = '428' THEN CHF=1; * CONGESTIVE HEART FAILURE;
IF ICD9DX3 IN ('410' '412') THEN MI=1; * MYOCARDIAL INFARCTION;

%MEND;


CHSCORE= MI + CHF + PVD + CEVD + DEMENT + COPD + RHEUM + PUD +
         MLDLD +DIAB + 2*HEMIPL + 2*CRF + 2*DMWCC + 2*NEOPLAS +
         3*MSLD+ 6*METS + 6*HIV ;
```

Appendix B

Berenson-Eggers Type of Service (BETOS) codes used in counting physician services

BETOS	Descriptions
M1A	OFFICE VISITS - NEW
M1B	OFFICE VISITS - ESTABLISHED
M2A	HOSPITAL VISIT - INITIAL
M2B	HOSPITAL VISIT - SUBSEQUENT
M2C	HOSPITAL VISIT - CRITICAL CARE
M3 E	MERGENCY ROOM VISIT
M4A	HOME VISIT
M4B	NURSING HOME VISIT
M5A	SPECIALIST - PATHOLOGY
M5B	SPECIALIST - PSYCHIATRY
M5C	SPECIALIST - OPHTHALMOLOGY
M5D	SPECIALIST - OTHER
M6	CONSULTATIONS

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1. Allen KB, Dowling RD, Fudge TL, et al. Comparison of transmyocardial revascularization with medical therapy in patients with refractory angina. *N Engl J Med.* Sep 30 1999;341(14):1029-1036.

2. Frazier OH, March RJ, Horvath KA. Transmyocardial revascularization with a carbon dioxide laser in patients with end-stage coronary artery disease. *N Engl J Med.* Sep 30 1999;341(14):1021-1028.

3. Allen KB, Dowling RD, DelRossi AJ, et al. Transmyocardial laser revascularization combined with coronary artery bypass grafting: a multicenter, blinded, prospective, randomized, controlled trial. *J Thorac Cardiovasc Surg.* Mar 2000;119(3):540-549.

4. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.

5. Deyo R, Cherkin D, Ciol M. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. *J Clin Epidemiol.* 1992;45:613-619.